Most Recent Modification 9/2014

REVLIMID[®] (lenalidomide)

NDA 021880

Celgene Corporation 86 Morris Avenue Summit, NJ 07901

Contact Information:

1-908-673-9000 www.celgene.com

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

1. GOALS

The goals of the REVLIMID risk evaluation and mitigation strategy are as follows:

- 1. To prevent the risk of embryo-fetal exposure to REVLIMID.
- 2. To inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for REVLIMID.

2. REMS ELEMENTS

2.1. Elements to Assure Safe Use

2.1.1. Healthcare providers who prescribe REVLIMID are specially certified.

Celgene will ensure that healthcare providers who prescribe REVLIMID are specially certified in the REVLIMID REMSTM program.

To become certified, each prescriber must complete the Prescriber Enrollment Form and agree to do the following:

- a. Provide patient counseling on the benefits and risks of REVLIMID therapy, including risks described in the BOXED WARNINGS.
- b. Enroll each patient by completing and submitting to the Celgene Customer Care Center via mail (86 Morris Avenue, Summit, NJ 07901), email (customercare@celgene.com), fax (1-888-432-9325), or online (www.celgeneriskmanagement.com), a signed Patient-Physician Agreement Form (PPAF) identifying the patient's risk category (see PPAFs for all six risk categories) for each new patient. In signing the PPAF, each prescriber acknowledges that they understand that REVLIMID is available only through the REVLIMID REMSTM program, and that they must comply with program requirements.
- c. Provide contraception and emergency contraception counseling with each new prescription prior to and during REVLIMID treatment.

- d. Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions.
- e. Report any pregnancies in female patients or female partners of male patients prescribed REVLIMID immediately to Celgene Drug Safety (or Celgene Customer Care Center, 1-888-423-5436).
- f. Complete a prescriber survey (phone or online) for every patient (new and follow-up), obtain a unique prescription authorization number for each prescription written, and include this authorization number on the prescription. The authorization number can be obtained by contacting the Celgene Customer Care Center, using the automated IVR system, or via the www.CelgeneRiskMangement.com website.
 - o For females of reproductive potential, authorization numbers are valid only for 7 days from date of last pregnancy test and 30 days from the date it is issued for all other patients.
- g. Facilitate compliance with the mandatory REVLIMID REMSTM program patient survey by instructing patients to complete the mandatory surveys (phone or online) at program specified frequencies.
- h. Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions.
- i. Contact a REVLIMID REMSTM program pharmacy certified by the REVLIMID REMSTM program to fill the REVLIMID prescription.
- j. Return all unused REVLIMID brought in by patients to Celgene Customer Care.
- k. Re-enroll patients in the REVLIMID REMSTM program if REVLIMID is required and previous therapy with REVLIMID has been discontinued for 12 consecutive months.

Celgene will:

- 1. Ensure that the REVLIMID REMS™ program materials including prescriber enrollment are available on the CelgeneRiskManagement.com website or can be obtained by contacting Celgene Customer Care Center at 1-888-423-5436
- 2. Maintain a secure database of all REVLIMID REMS $^{\text{\tiny TM}}$ program certified prescribers.
- 3. Monitor to ensure that only REVLIMID REMS[™] program certified prescribers are prescribing REVLIMID.
- 4. Monitor and ensure that patients have been assigned correctly to one of the following patient risk categories. Confirm risk category when completing the PPAFs during the patient enrollment process:
 - a. **Adult female of reproductive potential:** all females who are menstruating, amenorrheic from previous medical treatments, under 50 years, and/or perimenopausal.
 - b. **Female child of reproductive potential:** all females under 18 years who are menstruating.
 - c. **Adult female NOT of reproductive potential:** females who have had a natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy.
 - d. **Female child NOT of reproductive potential:** all females under 18 years who are not menstruating.
 - e. Adult males 18 years or older
 - f. Male child under 18 years
- 5. Monitor certified prescriber compliance with the REVLIMID REMS[™] program, including patient risk categorization and the appropriate corresponding counseling requirements, contraception requirements, pregnancy testing, and survey completion for all patients treated with REVLIMID.
- 6. Institute corrective action and prevent the certified prescriber from prescribing REVLIMID if the prescriber is found to be non-compliant with the REVLIMID REMS[™] program.

- 7. Train REVLIMID REMS[™] program certified prescribers in adverse experience reporting procedures, including the requirement to immediately report to Celgene any suspected embryo-fetal exposure to REVLIMID if a pregnancy occurs.
- 8. Ensure that once the prescriber submits the completed PPAF, the prescriber will receive a confirmation letter via fax or online to confirm the patient's enrollment and signify that the prescriber and patient surveys can be taken to receive an authorization number for the REVLIMID prescription (for all males, the PPAF is considered the initial survey). The authorization number is written on the REVLIMID prescription.
- 9. Ensure that, for subsequent prescriptions, the prescriber completes a telephone or online survey designed to look for signals of at-risk behavior (e.g., pending or outdated pregnancy test), report the patient's pregnancy test results, correct assignment of risk category, and confirm or re-enforce patient understanding of contraceptive requirements. The completion of the survey will allow the prescriber to obtain a new authorization number every time a prescription for REVLIMID is written.

The following materials are part of the REMS, and are appended:

- Prescriber Enrollment Form
- Patient Prescription Form
- Patient Prescription Form (Veterans Administration)
- Prescriber Guide to REVLIMID REMSTM Program
- Welcome Letter
- Celgene Risk Management.com website

2.1.2. REVLIMID will only be dispensed by pharmacies that are specially certified.

Celgene will ensure that REVLIMID is only dispensed from REVLIMID REMS™ program certified pharmacies. To become a certified pharmacy, the pharmacy must agree to do the following before filling a REVLIMID prescription:

- a. Only accept prescriptions with a prescription authorization number. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients.
- b. Dispense no more than a 4-week (28-day) supply, and require a new prescription from the patient prior to dispensing additional REVLIMID.
- c. Dispense subsequent prescriptions only if there are 7 days or less remaining on an existing REVLIMID prescription.
- d. Obtain a REVLIMID REMSTM confirmation number from the Celgene Customer Care Center (phone or online) and write this confirmation number on the prescription. The REVLIMID REMSTM confirmation number may be obtained using the following procedure:
 - 1.Enter the pharmacy identification number (NABP or DEA);
 - 2.Enter the prescription authorization number written on the prescription;
 - 3.Enter the number of capsules and milligram (mg) strength being dispensed;
 - 4.Dispense or ship the prescribed REVLIMID within 24 hours of obtaining and recording the REVLIMID REMSTM confirmation number and confirmation date.
- e. Dispense REVLIMID only after a REVLIMID REMSTM program confirmation number is obtained. If no confirmation is obtained, then no REVLIMID is dispensed. Contact the patient's physician and Celgene for further instruction.

- f. Accept unused REVLIMID (previously dispensed) from a patient or patient caregiver and return to Celgene Corporation for proper disposal.
- g. For each patient receiving treatment, retain a record of each REVLIMID prescription dispensed and the corresponding completed REVLIMID REMSTM Education and Counseling Checklist.
- h. Complete the checklist that applies to the REVLIMID REMSTM program patient risk category written on the front of the Education and Counseling Checklist for Pharmacies.
- i. Provide counseling to patients and/or guardians of patients under 18 years of age receiving REVLIMID treatment.
 - a. Counsel all patients and guardians of patients under 18 years of age on the following:
 - 1. The benefits and risks of REVLIMID therapy.
 - 2. Not sharing REVLIMID medication
 - 3. Not donating blood while taking REVLIMID, during dose interruptions, and for 4 weeks after stopping REVLIMID.
 - 4. Not to break, chew, or open REVLIMID capsules.
 - 5. Instructions on REVLIMID dose and administration.
 - 6. To read the REVLIMID REMSTM program education materials and encourage compliance with the requirements.
 - b. In addition to above, counsel Females of Reproductive Potential on the following:
 - 1. The potential for embryo-fetal toxicity with exposure to REVLIMID.
 - 2. Using 2 forms of effective birth control at the same time or abstaining from heterosexual sexual intercourse.
 - 3. Continuing to use 2 forms of birth control if REVLIMID therapy is interrupted and for at least 4 weeks after therapy is discontinued.
 - 4. Obtaining a pregnancy test weekly during the first 4 weeks of REVLIMID use, then a repeat pregnancy test every 4 weeks in females with regular menstrual cycles, and every 2 weeks in females with irregular menstrual cycles.
 - 5. The need to stop taking REVLIMID and notify their REVLIMID prescriber immediately if they become pregnant or suspect they may be pregnant.
 - c. In addition to items listed for all patients above, counsel **Males** receiving REVLIMID treatment about the potential for embryo-fetal toxicity with exposure to REVLIMID and the importance of using barrier contraception by wearing a latex or synthetic condom when engaging in sexual intercourse with a female of reproductive potential even if the male receiving REVLIMID has had a successful vasectomy.
 - 1. The need to not donate sperm while taking REVLIMID, during dose interruptions, and for 4 weeks after stopping REVLIMID.
 - d. Counsel the **Parent or legal guardian of Female Child NOT of reproductive potential** who is receiving REVLIMID treatment about the need to inform their REVLIMID prescriber when the child begins menses.

Before a certified pharmacy dispenses REVLIMID, Celgene will train the appropriate pharmacy staff:

- 1. About the REVLIMID REMSTM program
- 2. About the procedures for reporting adverse experiences to Celgene, including the requirement to immediately report to Celgene any suspected embryo-fetal exposure to REVLIMID if a pregnancy occurs.

The following materials are part of the REMS, and are appended:

- Pharmacy Guide to REVLIMID REMS™ Program
- Education and Counseling Checklist for Pharmacies
- Celgene REMS Programs Pharmacy Training: REVLIMID REMSTM
- Pharmacy Certification Quiz (the REVLIMID REMSTM Program)

2.1.3. Celgene will ensure that REVLIMID® will only be dispensed to patients enrolled in the REVLIMID REMSTM program with evidence or other documentation of safe-use conditions.

Celgene will ensure that all patients treated with REVLIMID are enrolled by a certified prescriber. The prescriber will enroll the patient by completing Patient-Physician Agreement Form and submitting the form via mail (86 Morris Avenue, Summit, NJ 07901), fax (1-888-432-9325), email (customercare@celgene.com) or online (www.celgeneriskmanagement.com) for each patient who receives REVLIMID. Each patient and/or guardian of patients under 18 years of age consents to participate in the program by:

- a. acknowledging that he or she understands that:
 - i. severe birth defects or death to an unborn baby may occur if a female becomes pregnant while she is receiving REVLIMID;
 - ii. REVLIMID must not be shared with anyone, even someone with similar symptoms;
 - iii. REVLIMID must be kept out of the reach of children and should NEVER be shared with females who are able to have children;
 - iv. they cannot donate blood while receiving REVLIMID including during dose interruptions, and for 4 weeks after stopping REVLIMID;
 - v. they might be asked to participate in the REVLIMID Pregnancy Exposure Registry; and
 - vi. they may be contacted by Celgene about following the rules of the REMS.
- b. In addition, each patient and/or guardian of patients under 18 years of age consents to participate in the program by:
 - i. agreeing to return unused REVLIMID to Celgene or their REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to them;
 - ii. agreeing to participate in a monthly (telephone or online) survey while on REVLIMID (with the exception of Adult Females Not of Reproductive Potential who are required to take a survey once every six months); and
 - iii. reviewing the REVLIMID REMSTM program educational materials and asking their prescriber any questions that have not been answered.

In addition, **Females and guardians of female children** must attest to their understanding of their/their child's reproductive potential, as categorized by the prescribing physician.

Females of Reproductive Potential and guardians of Female Children of Reproductive Potential will attest that they/their child:

- a. is not currently pregnant, and will try to refrain from becoming pregnant while receiving REVLIMID therapy and for at least 4 weeks after completely stopping REVLIMID therapy;
- b. must not take REVLIMID if pregnant, breastfeeding a baby, or not using birth control as defined in the REMS;

- c. will, unless abstinent, use contraception as defined within the REMS: for at least 4 weeks before starting REVLIMID, while receiving REVLIMID, during dose interruptions, and for at least 4 weeks after stopping REVLIMID;
- d. will have pregnancy testing done as ordered by the certified prescriber within 10 to 14 days and 24 hours prior to starting REVLIMID, every week for at least the first 4 weeks of REVLIMID therapy, and then every 4 weeks if the Female of Reproductive Potential has regular menstrual cycles, or every 2 weeks if the Female of Reproductive Potential has irregular menstrual cycles, while receiving REVLIMID;
- e. will immediately stop taking REVLIMID and inform the certified prescriber if the patient becomes pregnant, misses a menstrual period, experiences unusual menstrual bleeding, stops using contraception, or thinks for any reason that she might be pregnant; if the prescriber is not available, the Female of Reproductive Potential or guardian of a Female Child of Reproductive Potential can call the Celgene Customer Care Center at 1-888-423-5436 or the Emergency Contraception Hotline at 1-888-668-2528 for information on emergency contraception.

Males or Guardians of males will attest that they/their child will:

- a. never have unprotected sexual contact with a female who can become pregnant;
- b. wear a latex or synthetic condom every time the male patient has sexual contact with a female who is or who can become pregnant; continue condom use with sexual contact while the male patient is receiving REVLIMID treatment, during dose interruptions, and for 4 weeks after the male patient stops taking REVLIMID, even if the patient has had a successful vasectomy; and
- c. inform their certified prescriber if the male patient has unprotected sexual contact with a female who can become pregnant, or if they think for any reason that the male patient's sexual partner might be pregnant; the male patient or guardian of an underage male patient can call the Celgene Customer Care Center at 1-888-423-5436 or the Emergency Contraception Hotline at 1-888-668-2528 for information on emergency contraception;
- d. not donate sperm while taking (including dose interruptions) and for 4 weeks after stopping REVLIMID

The following appended materials are part of the REMS:

- Patient-Physician Agreement Form for Adult Male
- Patient-Physician Agreement Form for Male Child
- Patient-Physician Agreement Form for Adult Female Who Can Not Get Pregnant
- Patient-Physician Agreement Form for Adult Female Who Can Get Pregnant
- Patient-Physician Agreement Form for Female Child Who Can Not Get Pregnant
- Patient-Physician Agreement Form for Female Child Who Can Get Pregnant
- Patient Guide to REVLIMID REMSTM Program
- Emergency Contraception Brochure
- Patient Survey Reminder Card
- REVLIMID Risk Evaluation and Mitgation Strategy (REMS)TM Program Education and Safety Kit
- REVLIMID REMSTM Patient Resource Pack Envelope

2.1.4. Female patients or female partners of male patients receiving REVLIMID who report a pregnancy that occurred during REVLIMID therapy will be enrolled in the REVLIMID Pregnancy Exposure Registry.

Upon receiving a report of pregnancy from the REVLIMID REMSTM program, Celgene Pregnancy Prevention Plan programs in the rest of the world, clinical trials, or directly from a prescriber, a pharmacy, or a patient, Celgene will enroll the female patient or female partner of the male patient taking REVLIMID into the REVLIMID Pregnancy Exposure Registry. The objectives of the registry are to monitor pregnancy outcomes in female patients of reproductive potential and male patients' female partners who are exposed to REVLIMID and to understand why the REVLIMID REMSTM program was unsuccessful.

2.2. Implementation System

The implementation system will include the following:

- 1) Celgene will maintain a secure database of all certified entities, including enrolled patients and certified prescribers and pharmacies to monitor and evaluate implementation of the elements provided for in Sections 2.1.1, 2.1.2, and 2.1.3.
- 2) Celgene will monitor pharmacy certification compliance and address deviations by monitoring real time dispensing activity and conducting pharmacy audits.
 - a. The Celgene Customer Care Center will monitor the certified pharmacies in the manner described in the REMS supporting document to ensure only enrolled and authorized patients are receiving REVLIMID. If a certified pharmacy is found to be non-compliant with the REVLIMID REMSTM program, Celgene will institute corrective action and may de-activate pharmacies for which retraining has proven ineffective, removing them from the REVLIMID REMSTM program.
 - b. Celgene will perform regular audits of contract pharmacies participating in the REVLIMID REMSTM program. For pharmacies that have been in the program for more than two years, Celgene will perform a risk-based assessment to select which pharmacies will be audited. The REVLIMID REMSTM program compliance audits will be performed by internal auditors of Celgene and/or outside auditors contracted and trained by Celgene.
- 3) Celgene will monitor and ensure that the prescriptions are filled within the allowed timeframes.
- 4) Celgene Customer Care Center will address customer complaints received that are related to the REVLIMID REMSTM program and distribution and dispensing of REVLIMID.
- 5) Celgene will maintain a reporting and collection system for safety information that includes a process to monitor pregnancy testing results and pregnancy outcomes (should one occur) through the REVLIMID Pregnancy Exposure Registry and to understand why the REVLIMID REMSTM program was unsuccessful for the pregnancy case in question.
- 6) Based on monitoring and evaluation of these elements to assure safe use, Celgene will take reasonable steps to work to improve implementation of these elements as applicable.
- 7) Celgene will develop and follow written procedures related to the implementation of the REMS.

2.3. Timetable for Submission of Assessment Reports

Celgene will submit REMS assessments at six months and then annually following the initial approval date of the REMS (August 3, 2010). To facilitate inclusion for as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude

no earlier than 60 days before the submission date for that assessment. it will be received by the FDA on or before the due date.	Celgene will submit each assessment so

REVLIMID® (lenalidomide) Patient Prescription Form

Today's DateDate Rx Needed	Prescriber Name
Patient Last NamePatient First Name	State License Number
Phone Number ()	Prescriber Phone Number (Ext
Shipping Address	Fax Number ()
CityStateZip	Prescriber Address
Date of BirthPatient ID#	
Language Preference: □English □Spanish □Other	CityStateZip
Best Time to Call Patient: □AM □PM	Patient Type From PPAF (Check one)
Patient Diagnosis (ICD-10 Code)	☐Adult Female – NOT of Reproductive Potential
Patient Allergies	□Adult Female – Reproductive Potential
	□Adult Male
Other Current Medications	in emale child – Reproductive Potential
	Male Child
PRESCRIPTION INSURANCE INFORMATION (Fill out entirely and fax a copy of patient's insurance card, both sides)	TAPE PRESCRIPTION HERE PRIOR TO FAXING REFERRAL, OR COMPLETE THE FOLLOWING:
insurance cara, both sides)	Recommended Starting Dose: See below for dosage
Primary Insurance	Myelodysplastic Syndromes: The recommended starting dose of REVLIMID is 10 mg/day with water. Dosing is continued or modified based upon clinical and
Insured	laboratory
Policy #	findings. Multiple Myeloma and Mantle Cell Lymphoma: The recommended starting dose of
Group #	REVLIMID is 25 mg/day orally
Phone #	for Days 1 – 21 of repeated 28-day cycles. Dosing is continued or modified based upon clinical and laboratory findings
Rx Drug Card #	REVLIMID
Secondary Insurance	Dose Quantity Directions
Insured	□ 2.5 mg
Policy #	□ 5 mg
Group #	□ 10 mg
Phone #	·
Rx Drug Card #	□ 15 mg
	□ 20 mg
For further information on REVLIMID, please refer to the full	□ 25 mg
Prescribing Information	□Dispense as Written □Substitution Permitted
	NO REFILLS ALLOWED (Maximum Quantity = 28 days)
	Prescriber SignatureDate
	Authorization # Date
	(To be filled in by healthcare provider)

How to Fill a REVLIMID® (lenalidomide) Prescription

- 1. Healthcare provider (HCP) instructs female patients to complete initial patient survey
- 2. HCP completes survey
- 3. HCP completes patient prescription form
- 4. HCP obtains REVLIMID REMS™ (formerly known as the RevAssist® program) authorization number
- 5. HCP provides authorization number on patient prescription form
- 6. HCP faxes form, including prescription, to one of the Celgene Certified Pharmacy Network participants (see below)
- 7. HCP advises patient that a representative from the certified pharmacy will contact them
- 8. Certified pharmacy conducts patient education
- 9. Certified pharmacy obtains confirmation number
- 10. Certified pharmacy ships REVLIMID to patient with MEDICATION GUIDE

<u>Please see www.Celgene.com/PharmacyNetwork for the list of pharmacy participants</u> Information about REVLIMID and the REVLIMID REMS™ program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at <u>www.CelgeneRiskManagement.com</u>.



REVLIMID[®] is a registered trademark of Celgene Corporation. REVLIMID REMS™ is a trademark of Celgene Corporation. © 2013 Celgene Corporation 2/14 REMS-REV14358

REVLIMID® (lenalidomide) Patient Prescription Form – Veterans Administration (VA) ONLY

Today's DateDate Rx Needed	
Patient Last NamePatient First Name	Prescriber Name
Phone Number ()	State License Number
Shipping Address_	Prescriber Phone Number (Ext
CityStateZip	Fax Number ()
Date of BirthPatient ID#	Prescriber Address
	_
Language Preference: □English □Spanish □Other	CityStateZip
Best Time to Call Patient: □AM □PM	Patient Type From PPAF (Check one)
Patient Diagnosis (ICD-10 Code)	□Adult Female – NOT of Reproductive Potential
Patient Allergies	□Adult Female – Reproductive Potential
· · · · · · · · · · · · · · · · · · ·	□Adult Male
Other Current Medications	□Female Child – Not of Reproductive Potential
	□Female Child – Reproductive Potential
	☐Male Child
VA Pharmacy Information (Fill out entirely) VA Name Address	TAPE PRESCRIPTION HERE PRIOR TO FAXING REFERRAL, OR COMPLETE THE FOLLOWING: Recommended Starting Dose: See below for dosage
City State Zip VA Pharmacist Name Phone #	Myelodysplastic Syndromes: The recommended starting dose of REVLIMID is 10 mg/day with water. Dosing is continued or modified based upon clinical and laboratory findings.
Fax # McKesson Specialty Distribution Account # Shipping Information Check below for direct delivery to patient. If any information	Multiple Myeloma and Mantle Cell Lymphoma: The recommended starting dose of REVLIMID is 25 mg/day orally for Days 1 – 21 of repeated 28-day cycles. Dosing is continued or modified based upon clinical and laboratory findings. REVLIMID
is omitted, product will be shipped to the VA Pharmacy. □ Patient	Dose Quantity Directions
Name	,
Address State Zip	
	□ 5 mg
Phone	□ 10 mg
For further information on REVLIMID, please refer to the	□ 15 mg
full Prescribing Information	□ 20 mg
	□ 25 mg
	□Dispense as Written □Substitution Permitted
	NO REFILLS ALLOWED (Maximum Quantity = 28 days)
	Prescriber SignatureDate
	Authorization #Date
	(To be filled in by healthcare provider) Pharmacy Confirmation #Date (To be filled in by pharmacy)

How to Fill a REVLIMID® (lenalidomide) Prescription in the Veterans Administration (VA)

- 1. Healthcare Provider (HCP) instructs female patients to complete initial patient survey
- 2. HCP completes survey
- 3. HCP completes patient prescription form (include cell number for patient if possible)
- **4**. HCP obtains REVLIMID REMS[™] (formerly known as the RevAssist® program) authorization number
- 5. HCP provides authorization number on patient prescription form
- 6. HCP sends prescription to the VA Pharmacy

The following information must be filled in:

- Rx must include McKesson Specialty Distribution account number
- Rx must include VA address (Name, Street, City, State, ZIP)
- Rx must include VA Pharmacist contact information (Name, Phone and Fax #)
- 7. VA Pharmacist faxes the form, including prescription, to:

The REVLIMID REMS™ certified OncologyRx Care Advantage Specialty at 1-855-637-9446

- $\emph{8}$. HCP advises patient that a representative from REVLIMID REMS[™] certified pharmacy will be in contact
- 9. The REVLIMID REMS™ certified OncologyRx Care Advantage Pharmacist conducts patient education
- 10. The REVLIMID REMS™ certified OncologyRx Care Advantage Pharmacist obtains confirmation number
- 11. The REVLIMID REMS™ certified OncologyRx Care Advantage Pharmacist ships REVLIMID to the VA Pharmacy or directly to the patient with MEDICATION GUIDE
- 12. VA Pharmacist gives REVLIMID to VA patient with MEDICATION GUIDE

REVLIMID REMS™ Veterans Administration (VA) Pharmacy

OncologyRx Care Advantage Phone: 1-855-637-9433

Fax: 1-855-637-9446

Information about REVLIMID and the REVLIMID REMS™ program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at www.CelgeneRiskManagement.com.



REVLIMID® is a registered trademark of Celgene Corporation. REVLIMID REMS™ is a trademark of Celgene Corporation. © 2013 Celgene Corporation 2/14 REMS-REV14359

Prescriber Guide to

((REVLIMID REMSTM logo))

Risk Evaluation and Mitigation Strategy (REMS) [™] Program

Due to its structural similarity to thalidomide, a known teratogen, REVLIMID[®] (lenalidomide) is approved for marketing only under a restricted distribution program approved by the Food and Drug Administration. This program is called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)TM program (formerly known as the RevAssist[®] program).

This guide contains important information for prescribers about:

- The risks of REVLIMID, including a boxed warning for
 - o Embryo-fetal toxicity
 - o Hematologic toxicity
 - Venous and arterial thromboembolism
- The REVLIMID REMSTM program
 - o Prescriber Certification
 - o Patient Enrollment
 - o Contraceptive Requirements and Counseling for Patients
 - o Initial and Subsequent Prescription Requirements

REVLIMID REMSTM **Resources for Prescribers Include:**

- Prescriber Guide to REVLIMID REMSTM Program
- CD-ROM, including Patient-Physician Agreement Form and Patient Prescription Form Software and Installation Instructions
- Full Prescribing Information for REVLIMID

Table of contents About REVLIMID® (lenalidomide)
The REVLIMID REMS TM program4
Key points of the REVLIMID REMS TM program
Patient enrollment into REVLIMID REMS TM
program 5
Initial prescription requirements7
• All patients7
• Female patients7
o Females of reproductive potential8
o Females not of reproductive potential10
• Male patients
• Del 5q MDS patients
Initial mandatory confidential survey
Additional information for the prescriber
Subsequent prescription requirements
After the last dose of REVLIMID

Ordering English and non-English materials......14

Adverse drug experience reporting procedure for healthcare professionals.......15

About REVLIMID[®] (lenalidomide)

REVLIMID in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy.

REVLIMID is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

Risks of REVLIMID

REVLIMID has a Boxed Warning for embryo-fetal toxicity, hematologic toxicity, and deep venous thrombosis (DVT) and pulmonary embolism (PE) as well as risk of myocardial infarction and stroke.

Due to its structural similarity to thalidomide, a known teratogen, REVLIMID is contraindicated in pregnant females or females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID if they take adequate precautions to avoid pregnancy.

REVLIMID is associated with significant neutropenia and thrombocytopenia in patients with del 5q MDS. Many patients taking REVLIMID may require dose interruption and/or reduction. Evaluate your del 5q MDS patients closely for cytopenias. Patients on REVLIMID should have their complete blood counts monitored weekly for the first 8 weeks of therapy, and at least monthly thereafter.

There is a significant risk of deep venous thrombosis and pulmonary embolism as well as risk of myocardial infarction and stroke in patients with MM taking REVLIMID plus dexamethasone in combination. Monitor for and advise patients about the signs and symptoms of thromboembolism. Advise patients to seek immediate medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Thromboprophylaxis is recommended and the choice of regimen should be based on an assessment of the patient's underlying risks.

The REVLIMID REMSTM program

To avoid embryo-fetal exposure, REVLIMID $^{\otimes}$ (lenalidomide) is only available under a restricted distribution program called "REVLIMID Risk Evaluation and Mitigation Strategy (REMS)TM." Only certified prescribers can prescribe REVLIMID and only certified pharmacies can dispense REVLIMID in the REVLIMID REMSTM program.

In order to receive REVLIMID, all patients must be enrolled in REVLIMID REMSTM and agree to comply with the requirements of the REVLIMID REMSTM program. Information about REVLIMID and the REVLIMID REMSTM program can be obtained by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center toll-free at **1-888-423-5436**.

Key points of the REVLIMID REMSTM program

Prescriber

- The prescriber enrolls and becomes certified with Celgene for the REVLIMID REMSTM program
- The prescriber counsels patient on benefits and risks of REVLIMID
- The prescriber provides contraception and emergency contraception counseling
- The prescriber verifies negative pregnancy test for all female patients of reproductive potential
- The prescriber completes a REVLIMID[®] (lenalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
- The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category
- The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- The prescriber sends REVLIMID prescription to certified pharmacy

Pharmacy

- The pharmacy certifies with Celgene for REVLIMID REMSTM
- The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy dispenses REVLIMID to patient along with a Medication Guide

REVLIMID REMS TM patient enrollment

• Obtain, review, and complete the REVLIMID[®] (lenalidomide) Patient-Physician Agreement Form online at **www.CelgeneRiskManagement.com**, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**

- Prescribers who do not have access to a computer, or whose computer systems are not compatible with the software, will be provided with REVLIMID REMSTM program materials.
 For additional assistance, please contact the Celgene Customer Care Center or your Celgene Hematology Oncology Consultant
- Patient, parent/legal guardian, and/or authorized representative must read the REVLIMID[®] (lenalidomide) Patient-Physician Agreement Form in the language of their choice

Help Ensure Timely Processing of Each Prescription

Fill Out Form as Directed

- Write only in the designated areas on the REVLIMID® (lenalidomide) Patient-Physician Agreement Form
- The box next to each statement must be marked (with an "X") to indicate understanding
- The form must be completed and signed by both prescriber and patient

Instructions for Female Patients

• For female patients, the prescriber will need to provide information on whether the patient has been in surgical menopause, chemical menopause, or natural menopause for at least 24 months

Instructions for Minors

• If the patient is under 18 years of age, his or her legal guardian must read this material, mark the statement in each block of the form (with an "X") and agree to ensure compliance by signing and dating the form

Instructions for Incompetent Adult Patients

• For an incompetent adult patient, an authorized representative must sign the REVLIMID[®] (lenalidomide) Patient-Physician Agreement Form

REVLIMID REMSTM patient enrollment (continued)

- An authorized representative is a caretaker authorized under applicable state law to consent to treatment on the incompetent patient's behalf
- The authorized representative must read the material, mark the statements, and agree to ensure compliance by signing and dating the form
- If the authorized representative does not have the power of attorney, a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the REVLIMID® (lenalidomide) Patient-Physician Agreement Form. This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the REVLIMID® (lenalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the REVLIMID REMSTM program and is authorized to consent to treatment with REVLIMID on behalf of the patient

Send in Completed Forms

- Send the completed REVLIMID[®] (lenalidomide) Patient-Physician Agreement Form online through www.CelgeneRiskManagement.com, or to the Celgene Customer Care Center by faxing to 1-888-432-9325
- You will receive confirmation electronically or via fax to your office once the patient is enrolled
- Once REVLIMID[®] (lenalidomide) Patient-Physician Agreement Form is received, both female patients and prescriber can take their surveys as required. Male patients do not take initial surveys
- In the event that you do not receive this confirmation within 15 minutes, call the Celgene Customer Care Center

Note: If therapy with REVLIMID is discontinued for 12 consecutive months, the patient must enroll again in the REVLIMID REMSTM program. Follow the above procedures to re-enroll the patient.

Initial prescription requirements

ALL PATIENTS

- Provide comprehensive counseling on the benefits and risks of therapy with REVLIMID[®] (lenalidomide)
- Patients must be counseled on the potential risks of birth defects, other side effects, and important precautions associated with REVLIMID
- Provide counseling not to share REVLIMID capsules, and not to donate blood during treatment (including dose interruptions) and for 4 weeks after receiving their last dose of REVLIMID, as well as counseling on appropriate contraceptive use, including emergency contraception
- Provide patients with education materials provided in the REVLIMID REMSTM Patient Resource Pack
- Patients should be instructed to not extensively handle or open REVLIMID capsules
- Instruct patients to return unused REVLIMID capsules for disposal to Celgene or to their REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to them

FEMALE PATIENTS

Determine if female patient is of reproductive potential

Two categories:

1. Females of Reproductive Potential

All females who are menstruating, amenorrheic from previous medical treatments, under 50 years
of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential
category

2. Females Not of Reproductive Potential

 Females who have been in natural menopause for at least 24 consecutive months, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating

Initial prescription requirements (continued)

1. Females of Reproductive Potential

Pregnancy test requirements

- Obtain a **negative** pregnancy test 10 to 14 days prior to writing an initial prescription for REVLIMID[®] (lenalidomide) and again within 24 hours prior to writing an initial prescription for REVLIMID even if continuous abstinence is the chosen method of birth control
 - o The pregnancy test must be sensitive to at least 50 mIU/mL
 - o Pregnancy testing should occur weekly during the first 4 weeks of use
 - o Pregnancy testing should be repeated every 4 weeks if patient has regular menses or is amenorrheic, or every 2 weeks if irregular menses
 - If a patient misses her period or if there is any abnormality in menstrual bleeding,
 REVLIMID should be discontinued immediately. Obtain a pregnancy test and counsel the patient

- If pregnancy does occur during treatment, REVLIMID must be immediately discontinued. Any suspected embryo-fetal exposure to REVLIMID must be reported immediately to the FDA via the MedWatch number at 1-800-FDA-1088 and also to the Celgene Customer Care Center at 1-888-423-5436. The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling
- The patient must not breastfeed a baby while being treated with REVLIMID

Initial prescription requirements (continued) Patient Counseling on Contraception Requirements Contraception requirements

- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 methods of reliable contraception
- Reliable contraceptive methods include using at the same time at least 1 highly effective method and at least 1 additional method of birth control every time they have sex with a male
- Reliable contraceptive methods must be started at least 4 weeks before REVLIMID[®] (lenalidomide) therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

Effective Methods of Birth Control to Use Together

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD) Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants) Tubal ligation (having your tubes tied) Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	Male latex or synthetic condom Diaphragm Cervical cap

Remind all patients that not having any sexual intercourse is the only birth control method that is 100% effective.

• Unacceptable forms of contraception:

- o Progesterone-only "mini-pills"
- o IUD Progesterone T
- o Female condoms
- o Natural family planning (rhythm method) or breastfeeding
- o Fertility awareness
- Withdrawal
- o Cervical shield*
- Patients should be counseled that concomitant use of certain prescription drugs and/or dietary supplements can decrease the effects of hormonal contraception. If hormonal or IUD contraception is medically contraindicated, 2 other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after

^{*} A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception

Initial prescription requirements (continued)

2. Females Not of Reproductive Potential

- The patient must confirm that she is currently not pregnant, nor of reproductive potential as she has been in natural menopause for at least 24 months, or had a hysterectomy and/or bilateral oophorectomy
- The parent or guardian must confirm that a prepubertal female child is not now pregnant, nor is of reproductive potential as **menstruation has not yet begun**, and/or the child will not be engaging in heterosexual sexual contact for at least 4 weeks before REVLIMID[®] (lenalidomide) therapy, during therapy, and for at least 4 weeks after stopping therapy

MALE PATIENTS

- Male patients must be instructed to use a latex or synthetic condom every time they have sexual intercourse with a female of reproductive potential, even if they have undergone a successful vasectomy. The risk to the developing baby from the semen of male patients taking REVLIMD therapy is unknown
- Male patients must be instructed not to donate sperm during treatment (including dose interruptions) and for 4 weeks after their last dose of REVLIMID

Del 5q MDS PATIENTS

• Evaluate your del 5q MDS patients closely for cytopenias. Obtain a weekly CBC for the first 8 weeks of treatment, and at least monthly thereafter

Initial mandatory confidential survey

Females

• Instruct the female patient to complete a brief initial mandatory confidential survey at www.CelgeneRiskManagement.com, or by calling 1-888-423-5436. See page 12 for subsequent prescription requirements.

Males

• Males do not need to take the initial survey

Prescribers

Prescriber will complete a brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written. Be prepared to enter some of the following information:

- o Prescriber's identification number
- o Patient's identification number
- O Date and result of patient's pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
- o Average daily dose
- o Total number of days supply (cannot exceed 28 days)
- An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted

ADDITIONAL INFORMATION FOR THE PRESCRIBER

- Healthcare provider must send the prescription to a REVLIMID REMSTM certified pharmacy. To locate a certified pharmacy, please visit **www.Celgene.com/PharmacyNetwork**
- Prescribe no more than 4 weeks (28 days) of therapy, with no automatic refills

Subsequent prescription requirements

The <u>prescriber</u> must complete a brief mandatory confidential survey to obtain a new authorization number **every time** a prescription for REVLIMID[®] (lenalidomide) is written.

No automatic refills or telephone prescriptions are permitted. The patient risk category must be written on the prescription.

FEMALE PATIENTS

- Provide counseling as outlined in the "FEMALE PATIENTS" section on pages 7-10
- Follow pregnancy test requirements as outlined in the "Pregnancy test requirements" section on page 8
- Female patients must complete a brief mandatory confidential survey according to the following schedule:
 - o Before prescription is obtained
 - o Monthly
 - o Adult females of reproductive potential
 - o All female children
 - o Every 6 months
 - o Adult females not of reproductive potential

MALE PATIENTS

- Provide patient counseling as outlined in the "MALE PATIENTS" section on page 10
- Male patients must complete a brief mandatory confidential survey once a month
 - o Males do not complete an initial survey

Del 5q MDS PATIENTS

• Evaluate your del 5q MDS patients closely for cytopenias. Obtain a weekly CBC for the first 8 weeks of treatment and at least monthly thereafter

After the last dose of REVLIMID® (lenalidomide)

After patients have stopped taking REVLIMID, they must do the following:

ALL PATIENTS

- Must not share REVLIMID capsules—especially with females of reproductive potential
- Must return any unused REVLIMID capsules for disposal to Celgene or their REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to them
- Must not donate blood for 4 weeks after stopping REVLIMID

FEMALE PATIENTS

• Must not get pregnant for at least 4 weeks after stopping REVLIMID by using the appropriate contraceptives each time engaging in sexual activity with a male

MALE PATIENTS

- Must use a latex or synthetic condom for 4 weeks after stopping REVLIMID
- Must not donate sperm for 4 weeks after stopping REVLIMID

Ordering English and non-English materials

CALL CELGENE CUSTOMER CARE CENTER AT 1-888-423-5436

- Materials are available in 16 languages and include:
 - o REVLIMID® (lenalidomide) Patient-Physician Agreement Forms
 - o Patient Guide to REVLIMID REMS™ Program
 - o Mandatory confidential survey forms

Available languages:

Arabic	French	Japanese	Portuguese
Cambodian	German	Korean	Russian
Chinese	Greek	Laotian	Spanish
English	Italian	Polish	Vietnamese

• REVLIMID[®] (lenalidomide) Patient-Physician Agreement Forms, Patient Guide to REVLIMID REMSTM Program, and mandatory confidential survey forms requested will be faxed directly to the number you indicate. Please be prepared to provide:

Prescriber's:

Name

Identification Number

Full Address

Fax Number

Patient's:

Name

Full Address

Phone Number

Date of Birth

Identification Number

Diagnosis (most recent version of ICD code)

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of REVLIMID[®] (lenalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID to Celgene using any of the following methods.

REPORTING TO CELGENE

- Email: drugsafety@celgene.com
- Telephone: **1-908-673-9667**
- Toll-free: **1-800-640-7854** (Global Drug Safety & Risk Management) or **1-888-423-5436** (Celgene Customer Care Center)
- Fax: **1-908-673-9115**
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online: https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
- Telephone: 1-800-FDA-1088
- Fax: 1-800-FDA-0178
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

[Back Cover]

For more information about REVLIMID[®] (lenalidomide) and the REVLIMID REMSTM program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation 86 Morris Ave Summit, NJ 07901

REVLIMID is only available under a restricted distribution program, REVLIMID REMSTM.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

((Celgene logo)) ((REVLIMID REMSTM logo)) ((REVLIMID logo))

 $\begin{array}{ll} REVLIMID^{@} \ is \ a \ registered \ trademark \ of \ Celgene \ Corporation. \\ @\ 2014 \ Celgene \ Corporation \end{array}$

((REVLIMID REMSTM logo)

At-A-Glance

Important information about REVLIMID $^{\otimes}$ (lenalidomide) and the REVLIMID Risk Evaluation and Mitigation Strategy (REMS) $^{^{TM}}$ program

- REVLIMID is contraindicated in pregnant females and females capable of becoming pregnant.
 Females of reproductive potential may be treated with REVLIMID provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called "REVLIMID REMSTM" (formerly known as the RevAssist ® program)
- Only prescribers and pharmacies certified by the REVLIMID REMSTM program can prescribe and dispense REVLIMID to patients who are enrolled and meet all the conditions of the REVLIMID REMSTM program
- Information about REVLIMID and the REVLIMID REMSTM program can be obtained by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center toll-free at 1-888-423-5436

For more information about REVLIMID and the REVLIMID REMSTM program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

((Celgene logo)) (REVLIMID REMSTM logo)) ((REVLIMID logo))

Initial prescription (for all patients unless otherwise noted)

- 1. For females of reproductive potential, obtain 2 negative pregnancy tests sensitive to at least 50 mIU/mL, even if continuous abstinence is the chosen method of birth control. One test must be obtained 10 to 14 days and one test within 24 hours prior to writing an initial prescription for REVLIMID[®] (lenalidomide).
- 2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open REVLIMID capsules.
- 3. Obtain, review, and complete the REVLIMID[®] (lenalidomide) Patient-Physician Agreement Form online at **www.CelgeneRiskManagement.com**, with the CD-ROM software, or by calling the Celgene Customer Care Center for assistance at **1-888-423-5436**.
 - Males (adults and children)
 - Females of reproductive potential include <u>all females</u> who are menstruating, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category
 - Females not of reproductive potential include females who have been in natural menopause for at least 24 consecutive months, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating
- 4. Send the completed and signed REVLIMID[®] (lenalidomide) Patient-Physician Agreement Form online through **www.CelgeneRiskManagement.com**, or to the Celgene Customer Care Center by faxing to **1-888-432-9325**.
- 5. Instruct female patients to complete a brief initial mandatory confidential survey at **www.CelgeneRiskManagement.com**, or by calling **1-888-423-5436**, prior to prescriber obtaining an authorization number.
 - Males do not need to complete the initial survey
- 6. Complete a <u>prescriber</u> brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for **every patient** before each prescription is written.
 - You will need to enter the following information:
 - Prescriber's identification number
 - Patient's identification number
 - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)
- 7. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
- 8. Send the prescription to a certified pharmacy.

Subsequent prescriptions (for all patients unless otherwise noted)

- 1. For females of reproductive potential, obtain scheduled pregnancy tests weekly during the first 4 weeks of use; then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks.
- 2. Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open REVLIMID capsules.
- 3. Instruct patient to complete a brief mandatory confidential survey **as scheduled**, prior to prescriber obtaining an authorization number and filling the prescription.
 - Monthly:
 - Males (adults and children)
 - Females of reproductive potential (adults and children)
 - Female children not of reproductive potential
 - Every 6 months:
 - Adult females not of reproductive potential
- 4. Complete a <u>prescriber</u> brief mandatory confidential survey by visiting **www.CelgeneRiskManagement.com**, or calling the Celgene Customer Care Center at **1-888-423-5436**, for every patient before each prescription is written.
 - You will need to enter the following information:
 - Prescriber's identification number
 - Patient's identification number
 - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)
- 5. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
- 6. Send the prescription to a certified pharmacy.

REVLIMID $^{\otimes}$ is a registered trademark of Celgene Corporation. REVLIMID REMS TM is a trademark of Celgene Corporation. $^{\otimes}2013$ Celgene Corporation $^{1/13}$ REMS-REV12110

[Front]

((REVLIMID REMSTM logo)) Prescriber Enrollment Form

All prescribers <u>must</u> be certified to prescribe REVLIMID[®] (lenalidomide). To become certified the prescriber must:

- 1. Complete the Prescriber Enrollment Form which is required for REVLIMID REMSTM (formerly known as the RevAssist[®] program) certification.
- 2. Agree to steps on the following page that must be followed with every patient.

To submit this form electronically, please go to www.CelgeneRiskManagement.com.

To submit this form via fax, please complete the following page and fax it to 1-888-432-9325.

REVLIMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID provided adequate precautions are taken to avoid pregnancy.

Please review the steps on the following page that must be followed with every patient.

REVLIMID is only available under a restricted distribution program, REVLIMID REMS $^{\text{TM}}$. ((REVLIMID logo))

[Back]

REVLIMID REMSTM Prescriber Enrollment Form When prescribing REVLIMID[®] (lenalidomide), I agree to:

- Provide patient counseling on the benefits and risks of REVLIMID therapy, including Boxed Warnings
- Submit a completed REVLIMID[®] (lenalidomide) Patient-Physician Agreement Form for each new patient
- Provide contraception and emergency contraception counseling with each new prescription prior to and during REVLIMID treatment
- Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions
- Report any pregnancies in female patients or female partners of male patients prescribed REVLIMID immediately to Celgene Drug Safety (or Celgene Customer Care Center)
- Complete a mandatory and confidential <u>prescriber</u> survey online or by telephone for all patients and obtain a new authorization number for each prescription written and include this authorization number on the prescription
- Facilitate female patient compliance with an initial mandatory confidential <u>patient</u> survey online or by telephone
- Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- Contact a REVLIMID REMSTM certified pharmacy to fill the prescription
- Return to Celgene all REVLIMID capsules that are returned by patients. Shipping fees will be paid by Celgene Corporation. To arrange returns, call the Celgene Customer Care Center
- Remind patients to return all REVLIMID capsules to Celgene Corporation or their REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to them
- Re-enroll patients in the REVLIMID REMSTM program if REVLIMID is required and previous therapy with REVLIMID has been discontinued for 12 consecutive months

Please fill out the spaces below completely. Prescriber Name		
Degree: MD/DO/PA/NP/Fello		
Specialty		
Prescriber Identification Num	ber (eg, DEA Number, S	ocial Security Number, NPI Number, etc.
☐ Primary Office Name Attention		
		ZIP Code
		Fax
Email Address		
☐ Secondary Office Name		

Attention				
Address				
			ZIP Code	
Phone		Ext	Fax	
Email Address				
my prescriptions for REV	LIMID® (lenalidomide) v	ements of the REVLIMID Fivill not be honored at certifi	ied pharmacies.
Prescriber Signature			Date	
Return this form to the Ce	elgene Cu	stomer Care Ce	nter via fax or mail.	
Mail to: Celgene Customer C Phone: 1-888-423-5436 Fax: 1-888-432-9325 www.CelgeneRiskManage		,	enue, Summit, NJ 07901	
(Celgene logo)) ((REVLIMID REM	(S TM logo))	((REVLIMID	logo))	
REVLIMID [®] is a registered trademar	k of Celgene	Corporation. REVLIN	MID REMS™ is a trademark of Celger	e Corporation.
© 2013 Celgene Corporation	4/13	REMS-REV1329	1	

REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed REVLIMID for you. REVLIMID is available only through a restricted distribution program called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)TM (formerly known as the RevAssist[®] program). Before taking REVLIMID, you must read and agree to all of the instructions in the REVLIMID REMSTM program. If you are pregnant or become pregnant while taking REVLIMID, it is important for you to know that your unborn baby can have severe birth defects or even die.

REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.

REVLIMID causes a higher chance for blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism). To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine.

For more information, please see the REVLIMID Medication Guide.

INSTRUCTIONS

Before starting your treatment with REVLIMID, you will need to:

- 1. Complete sections 1 and 2 of this form and sign and date on page 6.
- 2. Read the REVLIMID REMSTM materials contained in the **Patient Resource Pack**.
- **3.** Keep a copy of this form for your records.

Authorized Representatives:

If the authorized representative does not have the power of attorney, a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the REVLIMID® (lenalidomide) Patient-Physician Agreement Form. This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the REVLIMID[®] (lenalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the REVLIMID REMSTM program and is authorized to consent to treatment with REVLIMID on behalf of the patient.

For more information, visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at 1-888-423-5436.

BAR CODE HERE

Page 1 of 6 (continued on next page)

REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement

I u	nderstand and confirm that:
	REVLIMID can cause severe birth defects or death to my unborn baby if I am pregnant or become pregnant during treatment
	I am not pregnant now and will not get pregnant while being treated with REVLIMID
	It is possible for me to get pregnant if:
	 I am having my period (am menstruating), or
	 My period has stopped because of my treatment
	 And I have sex with a male
	Not having sex is the only birth control method that is 100% effective
	I am not breastfeeding now and will not breastfeed while being treated with REVLIMID
	My REVLIMID prescription is only for me and is not to be shared with others
	I have read and understood the REVLIMID Patient Guide to REVLIMID REMS TM Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that REVLIMID may cause
	My healthcare provider has reviewed this information with me and answered any questions I have asked
	I may be contacted by Celgene to assist with the REVLIMID REMS TM program
	I will NOT donate blood while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID

BAR CODE HERE

Page 2 of 6

© 2014 Celgene Corporation 6/14 REMS-REV14431 (continued on next page)

REVLIMID® (lenalidomide) Patient-Physician Agreement Form

Adult Female Who Can Get Pregnant

☐ I will use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time I have sex with a male unless otherwise recommended by my doctor. My doctor may recommend that I use at the same time 2 different birth control methods **every time** I have sex with a male if I cannot use a hormonal or intrauterine device (IUD) method

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD) Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants) Tubal ligation (having your tubes tied) Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	Male latex or synthetic condom Diaphragm Cervical cap

- ☐ I will use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time I have sex with a male:
 - Starting at least 4 weeks before taking REVLIMID
 - While taking REVLIMID
 - During breaks (dose interruptions)
 - For at least 4 weeks after stopping REVLIMID

BAR CODE HERE

Page 3 of 6

© 2014 Celgene Corporation 6/14 REMS-REV14431

(continued on next page)

Adult Female Who Can Get Pregnant

	I will have pregnancy tests—performed by my healthcare provider—according to the schedule liste below:
	 10 to 14 days before receiving my first prescription for REVLIMID, and again 24 hours before receiving my first prescription for REVLIMID Every week during the first 4 weeks of my treatment with REVLIMID Every 4 weeks during the rest of my treatment if I have a regular menstrual cycle or no cycle at all—or—every 2 weeks if I have an irregular menstrual cycle
	I will have these pregnancy tests even if I do not get my period because of my treatment
	I will need to take another pregnancy test performed by my healthcare provider if my medication is dispensed within 7 days of taking my pregnancy test
	I will stop taking REVLIMID and call my doctor right away if I:
	 Become pregnant while taking REVLIMID, or Miss my period or have unusual menstrual bleeding, or Stop using birth control, or Think—for any reason—that I am pregnant or may be pregnant
	If I become pregnant or think I may be pregnant, I will call the Celgene Customer Care Center at 1-888-423-5436 or the Emergency Contraception Hotline at 1-888-668-2528 for information about emergency contraception if my doctor is not available
	I will complete the mandatory confidential monthly survey while taking REVLIMID
	I will keep my REVLIMID prescription out of the reach of children
	I will return any unused REVLIMID capsules for disposal to Celgene by calling 1-888-423-5436 . Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused REVLIMID capsules can also be returned to my REVLIMID prescriber or to the pharmacy that dispensed the REVLIMID to me
	BAR CODE HERE
Page 4 of 6	© 2014 Celgene Corporation 6/14 (continued on next page)

37

REMS-REV14431

Adult Female Who Can Get Pregnant

Section 2. Authorization

I understand and confirm that:

- By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support[®], and other companies
 - Analyze data for internal business purposes on the use of REVLIMID
 - Evaluate the effectiveness of the REVLIMID REMSTM program
 - Use in any other manner as required or permitted by law
 - Provide me with information about REVLIMID or my condition
- ☐ This authorization will remain in effect for 12 months after I stop REVLIMID. However, it may be <u>revoked</u> (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the REVLIMID REMSTM program
- ☐ Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want to participate in the REVLIMID REMSTM program. I understand that by refusing to participate in the REVLIMID REMSTM program, I will not be able to receive REVLIMID. However, I understand that I can speak with my doctor about other treatment options for my condition
- ☐ Upon signing this form, I authorize my healthcare provider to begin my treatment with REVLIMID



RevlimidREMS™



REVLIMID® is a registered trademark of Celgene Corporation. REVLIMID REMS™ is a trademark of Celgene Corporation.

BAR CODE HERE

© 2014 Celgene Corporation 6/14 REMS-REV14431 (continued on next page)

Page 5 of 6

Adult Female Who Can Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the REVLIMID REMSTM program, I will not be able to receive REVLIMID. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of REVLIMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if she has any questions regarding her treatment with REVLIMID (including appropriate birth control methods) and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the REVLIMID REMSTM program.

Pat	ient	Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Sex	Fax Number
Risk Category		
Menstru	ating:	
Surgical Me	nopause:	
Natural Menopause (24 months):		
Diagnosis		
Patient or Authorized Representative's Signature:		Prescriber's Signature :
Signature Date:		Signature Date:

Prescriber, please fax all pages of the completed form to 1-888-432-9325.

Give a copy of the form to the patient.

BAR CODE HERE

Page 6 of 6

© 2014 Celgene Corporation 6/14 REMS-REV14431

Adult Female Who Can Not Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed REVLIMID for you. REVLIMID is available only through a restricted distribution program called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS) $^{\rm TM}$ (formerly known as the RevAssist $^{\rm @}$ program). Before taking REVLIMID, you must read and agree to all of the instructions in the REVLIMID REMS $^{\rm TM}$ program.

Any unborn baby of a female taking REVLIMID can have severe birth defects or even die.

REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.

REVLIMID causes a higher chance for blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism). To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine.

For more information, please see the REVLIMID Medication Guide **INSTRUCTIONS**

Before starting your treatment with REVLIMID, you will need to:

- 1. Complete sections 1 and 2 of this form and sign and date on page 5.
- 2. Read the REVLIMID REMSTM materials contained in the **Patient Resource Pack**.
- **3.** Keep a copy of this form for your records.

Authorized Representatives:

If the authorized representative does not have the power of attorney, a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the REVLIMID® (lenalidomide) Patient-Physician Agreement Form. This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the REVLIMID® (lenalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the REVLIMID REMSTM program and is authorized to consent to treatment with REVLIMID on behalf of the patient.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

BAR CODE HERE

Page 1 of 5

© 2014 Celgene Corporation 6/14 REMS- REV14432

Adult Female Who Can Not Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement
I understand and confirm that:
☐ REVLIMID can cause severe birth defects or death to unborn babies of females taking REVLIMID
☐ I am not pregnant
☐ I am not able to get pregnant because:
 I have had both of my ovaries and/or my uterus removed, or
 I have been in menopause for at least 2 years
☐ My REVLIMID prescription is only for me and is not to be shared with others
☐ I have read and understood the REVLIMID Patient Guide to the REVLIMID REMS TM Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that REVLIMID may cause
☐ My healthcare provider has reviewed this information with me and answered any questions I have asked
☐ I may be contacted by Celgene to assist with the REVLIMID REMS [™] program
BAR CODE HERE

41

© 2014 Celgene Corporation 6/14 REMS- REV14432 (continued on next page)

Page 2 of 5

Adult Female Who Can Not Get Pregnant

Ιw	rill:
	I will complete the mandatory confidential survey every 6 months while taking REVLIMID
	I will keep my REVLIMID prescription out of the reach of children
	I will return any unused REVLIMID capsules for disposal to Celgene by calling 1-888-423-5436 .
	Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused REVLIMID capsules can also be returned to my REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to me
I w	rill not:
	I will not share my REVLIMID capsules with anyone even if they have symptoms like mine
	I will ${f not}$ donate blood while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID

BAR CODE HERE

Page 3 of 5 REV12116

© 2014 Celgene Corporation 6/14 REMS- REV14432

Adult Female Who Can Not Get Pregnant

Section 2. Authorization

I understand and confirm that:

- ☐ By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support[®], and other companies
 - Analyze data for internal business purposes on the use of REVLIMID
 - Evaluate the effectiveness of the REVLIMID REMSTM program
 - Use in any other manner as required or permitted by law
 - Provide me with information about REVLIMID or my condition
- ☐ This authorization will remain in effect for 12 months after I stop REVLIMID. However, it may be <u>revoked</u> (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the REVLIMID REMSTM program
- ☐ Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want to participate in the REVLIMID REMSTM program. I understand that by refusing to participate in the REVLIMID REMSTM program, I will not be able to receive REVLIMID. However, I understand that I can speak with my doctor about other treatment options for my condition
- ☐ Upon signing this form, I authorize my healthcare provider to begin my treatment with REVLIMID



RevlimidREMS™



 $REVLIMID^{@}\ is\ a\ registered\ trademark\ of\ Celgene\ Corporation.\ REVLIMID\ REMS^{TM}\ is\ a\ trademark\ of\ Celgene\ Corporation.$

BAR CODE HERE

Page 4 of 5 © 2014 Celgene Corporation 6/14 REMS- REV14432

Adult Female Who Can Not Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the REVLIMID REMSTM program, I will not be able to receive REVLIMID. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of REVLIMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if she has any questions regarding her treatment with REVLIMID and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the REVLIMID REMSTM program.

Pat	ient	Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Sex	Fax Number
Risk Category Menstruating: Surgical Menopause: Natural Menopause (24 months): Diagnosis		
Patient or Authorized Representative's Signature:		Prescriber's Signature :
Signature Date:		Signature Date:

Prescriber, please fax all pages of the completed form to 1-888-432-9325.

Give a copy of the form to the patient.

BAR CODE HERE

Page 5 of 5 © 2014 Celgene Corporation 6/14

Female Child Who Can Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed REVLIMID for your child.* REVLIMID is available only through a restricted distribution program called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)TM (formerly known as the RevAssist® program). Before taking REVLIMID, patients must read and agree to all of the instructions in the REVLIMID REMSTM program. If your child is pregnant or becomes pregnant while taking REVLIMID, it is important to know that the unborn baby can have severe birth defects or even die.

REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.

REVLIMID causes a higher chance for blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism). To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine.

For more information, please see the REVLIMID Medication Guide.

INSTRUCTIONS

Before your child starts treatment with REVLIMID, you will need to:

- 1. Complete sections 1 and 2 of this form and sign and date on page 6.
- 2. Read the REVLIMID REMSTM materials contained in the **Patient Resource Pack**.
- **3.** Keep a copy of this form for your records.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

BAR CODE HERE

Page 1 of 6 © 2014 Celgene Corporation 6/14 (continued on next page)

REMS- REV14433

Female Child Who Can Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Ag	greement	
I understand and co	nfirm that:	
becomes pregnant My child is not pre It is possible for m She has her per	egnant now and will not get pregnant while be by child to get pregnant if: riod (is menstruating) or has shown any sign of stopped because of treatment	ing treated with REVLIMID
☐ Not having sex is t	the only birth control method that is 100% efforts	ective
☐ My child's REVLI ☐ We have read and Program and/or ed information about ☐ My child's healthc questions we have ☐ We may be contact ☐ My child will NOT	eastfeeding now and will not breastfeed while IMID prescription is only for her and is not to understood the REVLIMID Patient Guide to tucational materials, including the Medication the possible health problems and side effects are provider has reviewed this information with asked ted by Celgene to assist with the REVLIMID I donate blood while taking REVLIMID (inclutopping REVLIMID	be shared with others the REVLIMID REMS TM Guide. These materials include that REVLIMID may cause ith us and answered any REMS TM program
	BAR CODE HERE	
Page 2 of 6	© 2014 Celgene Corporation 6/14 REMS- REV14433	(continued on next page)

46

Female Child Who Can Get Pregnant

I will tell my child that:

☐ She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male unless otherwise recommended by her doctor. Her doctor may recommend that she use **at the same time** 2 different birth control methods **every time** she has sex with a male if she cannot use a hormonal or intrauterine device (IUD) method

Unless she chooses not to have sexual intercourse with a male at any time (abstinence), she must always use acceptable birth control

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants) Tubal ligation (having your tubes tied)	Male latex or synthetic condom Diaphragm Cervical cap
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	

- ☐ She must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** she has sex with a male:
 - Starting at least 4 weeks before taking REVLIMID
 - While taking REVLIMID
 - During breaks (dose interruptions)
 - For at least 4 weeks after stopping REVLIMID

BAR CODE HERE

Page 3 of 6 © 2014 Celgene Corporation 6/14 (continued on next page)

REMS- REV14433

Female Child Who Can Get Pregnant

	BAR CODE HERE	
Celgene will pay capsules my child	y unused REVLIMID capsules for disposal to for the shipping costs. I understand that Celge did not take. Unused REVLIMID capsules capsiber, or to the pharmacy that dispensed the Revenue of the Pharmacy that dispensed the Pharmacy the Pharmacy that dispensed the Pharmacy that dispensed the Pharmacy that dispensed the Pharmacy th	ene cannot give me a refund for the an also be returned to my child's
☐ We will keep her	REVLIMID prescription out of the reach of o	other children
☐ We will complete	the mandatory confidential monthly survey v	while she is taking REVLIMID
 Misses her per Stops using bi Thinks—for a If she becomes pr Care Center at 1-3 	nant while taking REVLIMID, or iod or has unusual menstrual bleeding, or th control, or ny reason—that she is pregnant or may be pregnant or thinks she may be pregnant, I will compare the Emergency Contraception out emergency contraception if my child's definition of the Emergency contraception is my child of the Emergency contraception of the Emergency contraception is my child of the Emergency contraception of the Emergency	call the Celgene Customer on Hotline at 1-888-668-2528
☐ She must stop tak	ing REVLIMID and I will call her doctor righ	nt away if she:
	other pregnancy test performed by her healthc hin 7 days of taking her pregnancy test	are provider if her medication is
receiving her Every week d Every 4 week all—or—ever	before receiving her first prescription for REV first prescription for REVLIMID uring the first 4 weeks of her treatment with First 3 during the rest of her treatment if she has a ray 2 weeks if she has an irregular menstrual cycles pregnancy tests even if she does not get her	REVLIMID regular menstrual cycle or no cycle at ycle
listed below:	egnancy tests—performed by her healthcare p	novider—according to the senedure

Female Child Who Can Get Pregnant

Section 2. Authorization

T	under	stand	and	confirm	that.
1	unaers	Stallu	and	COMMITM	unata

- ☐ By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support[®], and other companies
 - Analyze data for internal business purposes on the use of REVLIMID
 - Evaluate the effectiveness of the REVLIMID REMSTM program
 - Use in any other manner as required or permitted by law
 - Provide me and my child with information about REVLIMID or my child's condition
- ☐ This authorization will remain in effect for 12 months after my child stops REVLIMID. However, it may be <u>revoked</u> (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the REVLIMID REMS[™] program
- ☐ Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- □ I may refuse to sign this authorization, which means that I do not want my child to participate in the REVLIMID REMSTM program. I understand that by refusing to have my child participate in the REVLIMID REMSTM program, she will not be able to receive REVLIMID. However, I understand that I can speak with my child's doctor about other treatment options for my child's condition
- ☐ Upon signing this form, I authorize my child's healthcare provider to begin my child's treatment with REVLIMID



RevlimidREMS™



REVLIMID® is a registered trademark of Celgene Corporation. REVLIMID REMS™ is a trademark of Celgene Corporation.

BAR CODE HERE

© 2014 Celgene Corporation 6/14 REMS- REV14433

Female Child Who Can Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the REVLIMID REMSTM program, she will not be able to receive REVLIMID. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of REVLIMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient and her parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and her parent/guardian if they have any questions regarding the child's treatment with REVLIMID (including appropriate birth control methods) and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the REVLIMID REMSTM program.

Patient		Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Sex	Fax Number
Risk Category		
Mensti Surgical Men	ruating:	
Natural Menopause (24 m		
Diagnosis		
Patient or Authorized Representative's Signature:		Prescriber's Signature :
Signature Date:		Signature Date:

Prescriber, please fax all pages of the completed form to 1-888-432-9325. Give a copy of the form to the parent/guardian.

BAR CODE HERE

Page 6 of 6 © 2014 Celgene Corporation 6/14

REMS-REV14433

Female Child Who Can Not Get Pregnant

Please read the following statements carefully.

Your doctor has prescribed REVLIMID for your child.* REVLIMID is available only through a restricted distribution program called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)TM (formerly known as the RevAssist[®] program). Before taking REVLIMID, patients must read and agree to all of the instructions in the REVLIMID REMSTM program. Any unborn baby of a girl taking REVLIMID can have severe birth defects or even die.

REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.

REVLIMID causes a higher chance for blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism). To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine.

For more information, please see the REVLIMID Medication Guide.

INSTRUCTIONS

Before your child starts treatment with REVLIMID, you will need to:

- 1. Complete sections 1 and 2 of this form and sign and date on page 5.
- 2. Read the REVLIMID REMSTM materials contained in the **Patient Resource Pack**.
- **3.** Keep a copy of this form for your records.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

BAR CODE HERE

Page 1 of 5 © 2014 Celgene Corporation 6/14 (continued on next page)

REMS- REV14434

51

Female Child Who Can Not Get Pregnant

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient	Agreement	
I understand and c	onfirm that:	
☐ REVLIMID can	cause severe birth defects or death to unborn bab	ies of females taking REVLIMID
☐ My child is not p	regnant	
☐ My child is not al	ble to get pregnant because she has not yet started	d her period (is not menstruating)
☐ My child's REVI	LIMID prescription is only for her and is not to b	e shared with others
and/or educationa	d understood the REVLIMID Patient Guide to the all materials, including the Medication Guide. The health problems and side effects that REVLIMITE.	ese materials include information
☐ My child's health we have asked	care provider has reviewed this information with	n us and answered any questions
☐ We may be conta	cted by Celgene to assist with the REVLIMID R	EMS TM program
	DAD CODE HEDE	
	BAR CODE HERE	
Page 2 of 5	© 2014 Celgene Corporation 6/14 REMS- REV14434	(continued on next page)

52

Female Child Who Can Not Get Pregnant

I will tell my child that	at:	
☐ We will complete the	ne mandatory confidential monthly survey wh	hile my child is taking REVLIMID
☐ We will keep my ch	nild's REVLIMID prescription out of the reac	ch of other children
Celgene will pay fo capsules my child d	unused REVLIMID capsules for disposal to 0 r the shipping costs. I understand that Celgen id not take. Unused REVLIMID capsules carber, or to the pharmacy that dispensed the RE	ne cannot give me a refund for the n also be returned to my child's
☐ She must not share	REVLIMID capsules with anyone even if the	ey have symptoms like hers
☐ She must not donat after stopping REV.	e blood while taking REVLIMID (including a LIMID	dose interruptions) and for 4 weeks
	BAR CODE HERE	
ge 3 of 5	© 2014 Calgary Corporation 6/14	(continued on next page)

REMS- REV14434

Female Child Who Can Not Get Pregnant

Section			41	•	4 •
Section	•	Δ1	ıth	0r179	ation
DUCLION	4.	Δ		VI 17.6	4417711

I understand and confirm that:

- ☐ By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support[®], and other companies
 - Analyze data for internal business purposes on the use of REVLIMID
 - Evaluate the effectiveness of the REVLIMID REMSTM program
 - Use in any other manner as required or permitted by law
- Provide me and my child with information about REVLIMID or my child's condition ☐ This authorization will remain in effect for 12 months after my child stops REVLIMID. However, it
- may be revoked (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the REVLIMID REMSTM program
- ☐ Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want my child to participate in the REVLIMID REMSTM program. I understand that by refusing to have my child participate in the REVLIMID REMS™ program, she will not be able to receive REVLIMID. However, I understand that I can speak with my child's doctor about other treatment options for my child's condition
- ☐ Upon signing this form, I authorize my child's healthcare provider to begin my child's treatment with **REVLIMID**



RevlimidREMS™



REVLIMID® is a registered trademark of Celgene Corporation. REVLIMID REMSTM is a trademark of Celgene Corporation.

BAR CODE HERE

Page 4 of 5 (continued on next page) © 2014 Celgene Corporation 6/14

REMS- REV114434

Female Child Who Can Not Get Pregnant

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the REVLIMID REMSTM program, she will not be able to receive REVLIMID. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of REVLIMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient and her parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and her parent/guardian if they have any questions regarding the child's treatment with REVLIMID and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the REVLIMID REMSTM program.

Pat	ient	Prescriber
Name		Name
Identification Number		Identification Number
Address		Address
Telephone Number		Telephone Number
Date of Birth	Sex	Fax Number
Risk Category Menstruating: Surgical Menopause: Natural Menopause (24 months):		
Diagnosis		
Patient or Authorized Representative's Signature:		Prescriber's Signature :
Signature Date:		Signature Date:

Prescriber, please fax all pages of the completed form to 1-888-432-9325.

Give a copy of the form to the parent/guardian.

BAR CODE HERE

Page 5 of 5	© 2014 Celgene Corporation 6/14	(continued on next page
	REMS- REV14434	

Adult Male

Please read the following statements carefully.

Your doctor has prescribed REVLIMID for you. REVLIMID is available only through a restricted distribution program called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS) $^{\text{TM}}$ (formerly known as the RevAssist $^{\text{®}}$ program). Before taking REVLIMID, you must read and agree to all of the instructions in the REVLIMID REMS $^{\text{TM}}$ program.

If a female you have sex with is pregnant or becomes pregnant by you while you are taking REVLIMID, it is important for you to know that your unborn baby can have severe birth defects or even die.

REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.

REVLIMID causes a higher chance for blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism). To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine.

For more information, please see the REVLIMID Medication Guide.

INSTRUCTIONS

Before starting your treatment with REVLIMID, you will need to:

- 1. Complete sections 1 and 2 of this form and sign and date on page 6.
- 2. Read the REVLIMID REMSTM materials contained in the **Patient Resource Pack**.
- **3.** Keep a copy of this form for your records.

Authorized Representatives:

If the authorized representative does not have the power of attorney, a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the REVLIMID® (lenalidomide) Patient-Physician Agreement Form. This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the REVLIMID® (lenalidomide) Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized representative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the REVLIMID REMSTM program and is authorized to consent to treatment with REVLIMID on behalf of the patient.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

BAR CODE HERE

Page 1 of 6 © 2014 Celgene Corporation 6/14 (continued on next page)

REMS- REV14435

56

Adult Male

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement				
I understand and confirm that:				
□ REVLIMID can cause severe birth defects or death to my unborn baby if I have sex with a female who is pregnant or who is able to get pregnant during my treatment □ My semen may contain REVLIMID even after I stop treatment. I must use a latex or synthetic condom every time I have sex with a female who is pregnant or who is able to get pregnant while taking REVLIMID (including dose interruptions), and for 4 weeks after stopping REVLIMID				
☐ Not having sex is the only birth control method that is 100% effective ☐ My REVLIMID prescription is only for me and is not to be shared with others				
☐ I have read and understood the REVLIMID Patient Guide to the REVLIMID REMS TM Program and/or educational materials, including the Medication Guide. These materials include information about the possible health problems and side effects that REVLIMID may cause				
☐ My healthcare provider has reviewed this information with me and answered any questions I have asked				
☐ I may be contacted by Celgene to assist with the REVLIMID REMS [™] program				

BAR CODE HERE

REMS- REV14435

Page 2 of 6 © 2014 Celgene Corporation 6/14 (continued on next page)

Adult Male

☐ I must use a latex or synthetic condom every time I have sex with a female who is pregnant or who is able to get pregnant, even if I have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
 □ I will use a latex or synthetic condom every time I have sex with a female who is pregnant or who is able to get pregnant: While taking REVLIMID During breaks (dose interruptions) For 4 weeks after stopping REVLIMID
 ☐ I will call my doctor right away if I: Have unprotected sex with a female who is pregnant or who is able to get pregnant Think—for any reason—that my sexual partner is pregnant or may be pregnant ☐ If my partner becomes pregnant or thinks she may be pregnant, I will call the Celgene Customer Care Center at 1-888-423-5436 or the Emergency Contraception Hotline at 1-888-668-2528 for information about emergency contraception if my doctor is not available ☐ If will call my doctor is pregnant or who is able to get pregnant or who is able to get pregnant or may be pregnant or may
☐ I will complete the mandatory confidential monthly survey while taking REVLIMID ☐ I will keep my REVLIMID prescription out of the reach of children ☐ I will return any unused REVLIMID capsules for disposal to Celgene by calling ☐ 1-888-423-5436. Celgene will pay for the shipping costs. I understand that Celgene cannot give me a refund for the capsules I did not take. Unused REVLIMID capsules can also be returned to my REVLIMID prescriber, or to the pharmacy who dispensed the REVLIMID to me

BAR CODE HERE

Page 3 of 6 © 2014 Celgene Corporation 6/14 (continued on next page)

REMS- REV14435

Adult Male

☐ I will not share my REVLIMID capsules with anyone even if they have symptoms lib	ke
mine	
☐ I will not donate blood or sperm while taking REVLIMID during breaks (dose interruptions) and for 4 weeks after stopping REVLIMID	
11 6	

Section 2. Authorization

I understand and confirm that:

- ☐ By signing this authorization, I allow my healthcare providers and pharmacies to share my medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support[®], and other companies
 - Analyze data for internal business purposes on the use of REVLIMID
 - − Evaluate the effectiveness of the REVLIMID REMSTM program
 - Use in any other manner as required or permitted by law
 - Provide me with information about REVLIMID or my condition

BAR CODE HERE

REMS- REV14435

Page 4 of 6 © 2014 Celgene Corporation 6/14

Adult Male

- ☐ This authorization will remain in effect for 12 months after I stop REVLIMID. However, it may be <u>revoked</u> (cancelled) earlier by me, at any time, once I inform my healthcare provider that I will no longer be a part of the REVLIMID REMSTM program
- ☐ Once my information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want to participate in the REVLIMID REMSTM program. I understand that by refusing to participate in the REVLIMID REMSTM program, I will not be able to receive REVLIMID. However, I understand that I can speak with my doctor about other treatment options for my condition
- ☐ Upon signing this form, I authorize my healthcare provider to begin my treatment with REVLIMID



RevlimidREMS™



REVLIMID® is a registered trademark of Celgene Corporation. REVLIMID REMSTM is a trademark of Celgene Corporation.

BAR CODE HERE

Page 5 of 6

© 2014 Celgene Corporation 6/14 REMS- REV14435

Adult Male

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if I do not follow all of the instructions regarding the REVLIMID REMSTM program, I will not be able to receive REVLIMID. I also understand that the information I provide on this form and as part of the surveys I will complete during treatment will be known by the manufacturer of REVLIMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient if he has any questions regarding his treatment with REVLIMID (including appropriate birth control methods) and has answered those questions to the patient's and prescriber's mutual satisfaction. Both patient and prescriber certify that they will comply with all of their obligations and responsibilities as described under the REVLIMID REMSTM program.

Patient	Prescriber
Name	Name
Identification Number	Identification Number
Address	Address
	Take est
Telephone Number	Telephone Number
Date of Birth	Fax Number
Sex	
Diagnosis	
Patient or Authorized Representative's Signature:	Prescriber's Signature :
Signature Date:	Signature Date:

Prescriber, please fax all pages of the completed form to 1-888-432-9325.

Give a copy of the form to the patient.

BAR CODE HERE

Page 6 of 6

© 2014 Celgene Corporation 6/14 REMS- REV14435

Male Child

Please read the following statements carefully.

Your doctor has prescribed REVLIMID for your child.* REVLIMID is available only through a restricted distribution program called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)TM (formerly known as the RevAssist[®] program). Before taking REVLIMID, patients must read and agree to all of the instructions in the REVLIMID REMSTM program.

If a female your child has sex with is pregnant or becomes pregnant by your child while he is taking REVLIMID, it is important to know that the unborn baby can have severe birth defects or even die.

REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.

REVLIMID causes a higher chance for blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism). To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine.

For more information, please see the REVLIMID Medication Guide.

INSTRUCTIONS

Before your child starts treatment with REVLIMID, you will need to:

- **1.** Complete sections 1 and 2 of this form and sign and date on page 6.
- 2. Read the REVLIMID REMSTM materials contained in the **Patient Resource Pack**.
- **3.** Keep a copy of this form for your records.

For more information, visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

*Throughout this form, the word *child* includes any child of whom you are the parent or guardian.

BAR CODE HERE

Page 1 of 6 © 2014 Celgene Corporation 6/14 REMS- REV14436

Male Child

Please read the following statements carefully. Mark the box (with an "X") if you agree with the statement. Please do not mark or write outside of designated areas.

Section 1. Patient Agreement				
I understand and conf	irm that:			
with a female who is My child's semen may or synthetic condom get pregnant while the after stopping REVL Not having sex is the My child's REVLIM We have read and under the program and/or eductional include information acause My child's healthcar questions we have as	e only birth control method that is 100% effective and prescription is only for him and is not to be a prescription is only for him and is not to be a prescription of the REVLIMID Patient Guide to the Relational materials, including the Medication Guide about the possible health problems and side effective provider has reviewed this information with use	nis treatment ment. He must use a latex gnant or who is able to ions), and for 4 weeks e shared with others EVLIMID REMS TM de. These materials cts that REVLIMID may s and answered any		
 Page 2 of 6	BAR CODE HERE © 2014 Celgene Corporation 6/14	(continued on next page)		
<i>U</i>	REMS- REV14436	(11 11		

Male Child

ī	will	tell	mv	child	that:

He must use a latex or synthetic condom every time he has sex with a female who is pregnant or who is able to get pregnant, even if he has had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
He must use a latex or synthetic condom every time he has sex with a female who is pregnant or who is able to get pregnant:
 While taking REVLIMID During breaks (dose interruptions) For 4 weeks after stopping REVLIMID
I will call his doctor right away if he:
 Has unprotected sex with a female who is pregnant or who is able to get pregnant Thinks—for any reason—that his sexual partner is pregnant or may be pregnant
If my child's partner becomes pregnant or thinks she may be pregnant, I will call the Celgene Customer Care Center at 1-888-423-5436 or the Emergency Contraception Hotline at 1-888-668-2528 for information about emergency contraception if my child's doctor is not available
We will complete the mandatory confidential monthly survey while my child is taking REVLIMID
We will keep his REVLIMID prescription out of the reach of other children
We will return any unused REVLIMID capsules to Celgene by calling 1-888-423-5436 . Celgene will pay for the shipping costs. I understand that Celgene cannot give us a refund for the capsules my child did not take. Unused REVLIMID capsules can also be returned to my child's REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to my child

BAR CODE HERE

Page 3 of 6 © 2014 Celgene Corporation 6/14 (continued on next page)
REMS- REV14436

Male Child

☐ He must **not** share his REVLIMID capsules with anyone even if they have symptoms like his ☐ He must **not** donate blood or sperm while taking REVLIMID, during breaks (dose interruptions), and for 4 weeks after stopping REVLIMID

Section 2. Authorization

I understand and confirm that:

- ☐ By signing this authorization, I allow my child's healthcare providers and pharmacies to share my child's medical and other health information with Celgene Corporation and other companies that Celgene works with to:
 - Coordinate the delivery of products and services available from pharmacies and Celgene patient assistance programs, including Celgene Patient Support[®], and other companies
 - Analyze data for internal business purposes on the use of REVLIMID
 - Evaluate the effectiveness of the REVLIMID REMSTM program
 - Use in any other manner as required or permitted by law
 - Provide me and my child with information about REVLIMID or my child's condition

BAR CODE HERE

Page 4 of 6

© 2014 Celgene Corporation 6/14 REMS- REV14436

Male Child

- ☐ This authorization will remain in effect for 12 months after my child stops REVLIMID. However, it may be <u>revoked</u> (cancelled) earlier by me, at any time, once I inform my child's healthcare provider that my child will no longer be a part of the REVLIMID REMSTM program
- ☐ Once my child's information is shared as noted above, and to process and coordinate the delivery of product, there is no guarantee that the person receiving the information will not share it with another party
- ☐ I may refuse to sign this authorization, which means that I do not want my child to participate in the REVLIMID REMSTM program. I understand that by refusing to have my child participate in the REVLIMID REMSTM program, he will not be able to receive REVLIMID. However, I understand that I can speak with my child's doctor about other treatment options for my child's condition
- ☐ Upon signing this form, I authorize my child's healthcare provider to begin my child's treatment with REVLIMID



RevlimidREMS™



REVLIMID® is a registered trademark of Celgene Corporation. REVLIMID REMS™ is a trademark of Celgene Corporation.

BAR CODE HERE

Page 5 of 6

© 2014 Celgene Corporation 6/14 REMS- REV14436

Male Child

Section 3. Authorization to Start Treatment

I have read the information on this form or it has been read aloud to me in the language of my choice. I understand that if my child does not follow all of the instructions regarding the REVLIMID REMSTM program, he will not be able to receive REVLIMID. I also understand that the information we provide on this form and as part of the surveys we will complete during treatment will be known by the manufacturer of REVLIMID and the Food and Drug Administration (FDA).

I agree that the prescriber has fully explained to the patient and his parent/guardian the nature, purpose, and risks of the treatment described above, especially the potential risks to females who can get pregnant. The prescriber has asked the patient and his parent/guardian if they have any questions regarding the child's treatment with REVLIMID (including appropriate birth control methods) and has answered those questions to the patient's, parent/guardian's, and prescriber's mutual satisfaction. The patient, parent/guardian, and prescriber certify that they will comply with all of their obligations and responsibilities as described under the REVLIMID REMSTM program.

Patient	Prescriber
Name	Name
Identification Number	Identification Number
Address	Address
Telephone Number	Telephone Number
Date of Birth	Fax Number
Sex	
Diagnosis	
Patient or Authorized Representative's Signature:	Prescriber's Signature :
Signature Date:	Signature Date:

Prescriber, please fax all pages of the completed form to **1-888-432-9325**.

Give a copy of the form to the parent/guardian.

BAR CODE HERE

Page 6 of 6

© 2014 Celgene Corporation 6/14 REMS- REV14436 [Housing Unit Cover Front Flap]

((REVLIMID REMSTM logo))

REVLIMID Risk Evaluation and Mitigation Strategy (REMS) $^{\rm TM}$ program education and prescribing safety kit

[Housing Unit Cover]

Risks of REVLIMID® (lenalidomide)

- REVLIMID is similar to the medicine thalidomide (THALOMID[®]). Thalidomide can cause severe life-threatening birth defects. If REVLIMID is used during pregnancy, it can cause birth defects or embryo-fetal death. REVLIMID must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking REVLIMID
- REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients
- REVLIMID causes a higher chance for blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism). To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine

REVLIMID in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy.

REVLIMID is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1—risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

((REVLIMID logo))

[Housing Unit Spine]

REVLIMID Risk Evaluation and Mitigation Strategy $(REMS)^{\text{TM}}$ program education and prescribing safety kit

[Housing Unit Back Cover] ((REVLIMID REMSTM logo))

Prescriber quick reference guide

- 1. The prescriber provides comprehensive counseling.
- 2. The prescriber verifies negative pregnancy test for <u>all</u> female patients of reproductive potential.
- 3. The prescriber completes REVLIMID[®] (lenalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene.
- 4. Female patients complete initial mandatory confidential survey by:
 - Visiting www.CelgeneRiskManagement.com, or
 - Calling Celgene Customer Care Center at 1-888-423-5436

Male patients do not need to complete the initial survey.

<u>All patients</u> must complete subsequent mandatory confidential surveys as outlined in the Prescriber Guide to REVLIMID REMSTM Program (formerly known as the RevAssist[®] program).

- 5. The prescriber completes mandatory confidential survey and receives authorization number by:
 - Visiting www.CelgeneRiskManagement.com, or
 - Calling Celgene Customer Care Center at 1-888-423-5436
- 6. The prescriber writes REVLIMID prescription and includes authorization number and patient risk category.
- 7. The prescriber sends prescription to certified pharmacy.

This flow sheet should be used only as a quick reference and only after reviewing all of the REVLIMID REMSTM procedures.

REVLIMID is only available under a restricted distribution program, REVLIMID REMS $^{\mathrm{TM}}$.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

((Celgene logo)) ((REVLIMID REMSTM logo)) ((REVLIMID logo))

REVLIMID® is a registered trademark of Celgene Corporation. REVLIMID REMS TM is a trademark of Celgene Corporation. © 2014 Celgene Corporation 6/14 REMS-REV14429

((REVLIMID REMS logo))

Program for REVLIMID® (Ienalidomide) Education and Prescribing Safety

Dear Prescriber:

Enclosed are your REVLIMID REMS™ education materials.

Celgene Corporation is pleased to provide you with the enclosed materials for use in the REVLIMID REMS™ program (formerly known as the RevAssist® program). Important Information about the REVLIMID REMS™ program

- To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called "REVLIMID REMS™"
- Lenalidomide is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with lenalidomide provided adequate precautions are taken to avoid pregnancy
- Male Patients: Clinical data has demonstrated the presence of lenalidomide in human semen. Male patients taking REVLIMID should not donate sperm. Males receiving REVLIMID must always use a latex or synthetic condom during any sexual contact with females of reproductive potential even if they have undergone a successful vasectomy
- Only prescribers and pharmacies certified with REVLIMID REMS[™] can prescribe and dispense REVLIMID to patients who are enrolled and meet all the conditions of the REVLIMID REMS[™] program

As a prescriber certified with the REVLIMID REMS™ program, please review and familiarize yourself with the contents of the enclosed REVLIMID REMS™ Kit:

Prescriber Materials

- REVLIMID REMS™ software and Installation Guide
- Prescriber Guide to REVLIMID REMS™ Program
- REVLIMID Full Prescribing Information

Patient Materials (Patient Resource Pack)

- Patient Guide to REVLIMID REMS™ Program
- Emergency Contraception Brochure
- MEDICATION GUIDE

To order additional Patient Resource Packs, or if you have any questions about using the enclosed software, please call the Celgene Customer Care Center at 1-888-423-5436.

Sincerely,

Jerome B. Zeldis, MD, PhD Chief Medical Officer

Enclosures

Risks of REVLIMID® (lenalidomide)

 REVLIMID is similar to the medicine thalidomide (THALOMID[®]). Thalidomide can cause severe life-threatening birth defects. If REVLIMID is used during pregnancy, it

- can cause birth defects or embryo-fetal death. REVLIMID must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking REVLIMID
- REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients
- REVLIMID causes a higher chance for blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism). To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine

REVLIMID in combination with dexamethasone is indicated for the treatment of multiple myeloma (MM) patients who have received at least one prior therapy.

REVLIMID is indicated for patients with transfusion-dependent anemia due to Low- or Intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

((Celgene logo)) ((REVLIMID REMS™ logo)) ((REVLIMID logo)

REVLIMID[®] is a registered trademark of Celgene Corporation. REVLIMID REMS™ is a trademark of Celgene Corporation.

©2014 Celgene Corporation 6/14 REMS-REV14428

[Front Cover]

Pharmacy Guide to $((REVLIMID\ REMS^{^{TM}}\log o))$ Risk Evaluation and Mitigation Strategy $(REMS)^{^{TM}}$ Program

Important information about REVLIMID $^{\otimes}$ (lenalidomide) and the REVLIMID REMSTM Program

- REVLIMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called "REVLIMID REMSTM" (formerly known as the RevAssist[®] program)
- Only prescribers and pharmacists certified with the REVLIMID REMS[™] program can
 prescribe and dispense the product to patients who are enrolled and meet all the conditions of
 the REVLIMID REMS[™] program
- Dispensing pharmacists must be educated on the REVLIMID REMSTM program and on dispensing procedures for REVLIMID
- Information about REVLIMID and the REVLIMID REMS™ program can be obtained by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center toll-free at 1-888-423-5436

((REVLIMID logo))

Table of contents

Guidelines for ordering, counseling, and dispensing REVLIMID® (lenalidomic	de)
	3
REVLIMID Risk Evaluation and Mitigation Strategy (REMS) TM Education are Checklist for Pharmacies	nd Counseling
Rules for dispensing and shipping	6
Adverse drug experience reporting procedure for healthcare professionals.	7

Guidelines for ordering, counseling, and dispensing REVLIMID[®] (lenalidomide)

Dispensing pharmacies must be certified in the REVLIMID REMSTM program with Celgene and must be educated in the following dispensing procedures.

Step 1. Review incoming REVLIMID prescriptions

- A. Only accept prescriptions with an authorization number and patient risk category written on them.
 - Authorization numbers are valid for 7 days from the date of last pregnancy test for female patients of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted
 - Faxed prescriptions are permissible depending on state laws
- B. Make sure the prescription is signed and dated.
- C. Confirm the prescription is written for a 4-week (28-day) supply or less.
- D. For subsequent prescriptions, verify there are 7 days or less remaining of therapy on the existing prescription.

Step 2. Counsel patient

- A. Make sure a **certified REVLIMID REMS**TM counselor counsels the patient.
- B. Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist and ensure the form is signed and dated. Ensure the appropriate boxes are checked off. Retain a copy of the checklist and record of the associated prescription.
- C. If the patient mentions adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID, make sure to document these experiences using acceptable documentation as noted on the checklist.
 - Acceptable documentation examples:
 - 1. Celgene Adverse Drug Event form and fax confirmation
 - 2. Pharmacy log

D. Report adverse drug experiences that are suspected to be associated with the use of REVLIMID to Celgene Drug Safety within 24 hours. See the Adverse Drug Experience Reporting Procedure on page 7 for more information.

Guidelines for ordering, counseling, and dispensing REVLIMID® (lenalidomide) (continued)

Step 3. Obtain confirmation number from Celgene Customer Care

- A. Prior to each prescription, contact Celgene Customer Care at **1-888-423-5436**, available 24 hours a day, 7 days a week. Eligible pharmacies may also use the Celgene REMS Pharmacy Portal at **www.CelgeneREMSPharmacyPortal.com**. Call your Celgene Account Manager to see if your pharmacy is eligible.
 - Enter the pharmacy NABP number or DEA number
 - Enter the authorization number written on the prescription
 - Enter the number of capsules and milligram strength being dispensed
- B. Write the confirmation number and the date of receipt on the prescription. The confirmation number is only valid for 24 hours.
- C. If you do not obtain a confirmation number, do not dispense REVLIMID.

Step 4. Dispensing

- A. No Refills. A new prescription is required for each dispense. **Dispense subsequent** prescriptions only if there are 7 days or less remaining of therapy on the existing prescription.
- B. Ensure the confirmation number has not expired, ie, dispense within 24 hours from confirmation number receipt. If more than 24 hours have elapsed, **Do Not Dispense**. You must call Celgene Customer Care at **1-888-423-5436** to cancel the first confirmation number and obtain a new confirmation number. For female patients of reproductive potential, ship the same day or hand to the patient within 24 hours.
- C. Dispense each prescription with a Medication Guide and maintain a record on acceptable documentation.
 - Acceptable documentation examples:
 - 1. Signed Education and Counseling Checklist (if counseling pharmacist and dispensing pharmacist are the same)
 - 2. Pharmacy log
- D. Document the dispense date and maintain a record on acceptable documentation.
 - Acceptable documentation examples:
 - 1. Shipping receipt
 - 2. Pharmacy dispensing log

Guidelines for ordering, counseling, and dispensing REVLIMID® (lenalidomide) (continued)

- E. Dispense no more than a 4-week (28-day) supply. A new prescription is required for each dispense. No automatic refills or telephone prescriptions are permitted.
- F. A signature is required for all shipping and dispense if picked up by patient.

Step 5. Perform drug accountability

- A. Pharmacy shall keep an inventory log for REVLIMID, by strength, reflecting its on-hand inventory at all times.
- B. Do not transfer REVLIMID to another pharmacy without prior authorization from Celgene.
- C. Accept unused REVLIMID (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper disposal.

REVLIMID Risk Evaluation Mitigation Strategy (REMS)TM **Education and Counseling Checklist for Pharmacies**

Ensure your patients know the risks

Before you are able to fill a prescription for REVLIMID [®] (lenalidomide), a checklist for each patient must be completed based on the patient risk category (written on the front of the Patient Prescription Form). When completing the checklist, be sure all the appropriate boxes are checked off ($[\checkmark]$) and the form is signed and dated. All boxes and spaces must be marked or filled in during counseling with the patient for every prescription. Retain a copy of the checklist and record of the associated prescription.

Be prepared to provide the following information for each checklist: ((IMAGE OF CHECKLIST))

Authorization Number Confirmation Number Confirmation Date
Pharmacy Name Pharmacy Address (including City, State, ZIP Code)

Counselor Name Work Phone Number Extension

Patient Name Patient Date of Birth

Rules for dispensing and shipping

Making sure before you release REVLIMID

DO NOT DISPENSE OR SHIP REVLIMID TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:

- Prescription has an authorization number and patient risk category written on it
- You have obtained a confirmation number and a confirmation date
- You are shipping the product within 24 hours of obtaining the confirmation number and requesting confirmation of receipt. For females of reproductive potential, the product must be shipped the same day the confirmation number is obtained
- The Medication Guide is included with the prescription
- You confirm the prescription is no more than a 4-week (28-day) supply and there are 7 days or less remaining on the existing REVLIMID prescription

For further information about REVLIMID, please refer to the full Prescribing Information, enclosed.

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of REVLIMID[®] (lenalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID to Celgene using any of the following methods.

REPORTING TO CELGENE

- Email: drugsafety@celgene.com
- Telephone: **1-908-673-9667**
- Toll-free: 1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Celgene Customer Care Center)
- Fax: 1-908-673-9115
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online at: https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
- Telephone: 1-800-FDA-1088
- Fax: 1-800-FDA-0178
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

[Back Cover]

For more information about REVLIMID[®] (lenalidomide) and the REVLIMID REMSTM program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation 86 Morris Ave Summit, NJ 07901

REVLIMID is only available under a restricted distribution program, REVLIMID REMS $^{\rm TM}$.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.

 $((Celgene\ logo)) \qquad \qquad ((REVLIMID\ REMS^{TM}\ logo)) \qquad \qquad ((REVLIMID\ logo))$

REVLIMID® is a registered trademark of Celgene Corporation. REVLIMID REMS™ is a trademark of Celgene Corporation.

© 2014 Celgene Corporation 6/14 REMS-REV14441

Education and Counseling Checklist for Pharmacies

REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the RevAssist® program) education and prescribing safety

Authorization No.: Pharmacy Name: Pharmacy Address:	Confirmation No	: Confirmation Date:
Counselor Name: Patient Name: Risk Category:	Work Phone: Ex Date of Birth:	.t.:
		roductive potential nat they will receive the Medication Guide along with
I COUNSELED AD ☐ Potential embryo-f	ULTS AND CHILDI etal toxicity	REN ON:
☐ Not taking REVLI	MID® (lenalidomide)	if pregnant or breastfeeding
(birth controls pills vasectomy—and a	s, hormonal patches, in t least 1 additional effe diaphragm, or cervica	effective method—tubal ligation, IUD, hormonal effections, vaginal rings, or implants), or partner's ective method of birth control—male latex or l cap—every time they have sex with a male, or
effective method o taking REVLIMID	f birth control beginni , during dose interrup	ast 1 highly effective method and at least 1 additional and at least 4 weeks before taking REVLIMID, while tions, and for at least 4 weeks after stopping with a male, or abstaining from sex with a male
4 weeks of use. The rest of their treatment	ereafter, pregnancy te ent in females with reg	by their healthcare provider—weekly during the first sting should be repeated every 4 weeks during the gular menstrual cycles or no cycle at all. If menstrual g should occur every 2 weeks

☐ The need to stop taking REVLIMID right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately
☐ Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism as well as risk of myocardial infarction and stroke
☐ The need for del 5q MDS patients to schedule a blood test every week for the first 8 weeks and monthly thereafter to monitor blood counts while taking REVLIMID
$\hfill\square$ Not sharing REVLIMID capsules with anyone—especially with females who can get pregnant
$\hfill\square$ Not donating blood while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID
☐ Not breaking, chewing, or opening REVLIMID capsules
☐ Instructions on REVLIMID dose and administration
Milligram (mg) Strength Number of Capsules Dispensed
FEMALE CHILDREN (<18 YEARS OF AGE):
☐ Parent or legal guardian must have read the REVLIMID REMS TM education material and agreed to ensure compliance
Checklist for female patients not of reproductive potential (natural menopause for at least 24 consecutive months, a hysterectomy, and/or bilateral oophorectomy) □ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription
I COUNSELED ADULTS AND CHILDREN ON: ☐ Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism as well as risk of myocardial infarction and stroke
☐ The need for del 5q MDS patients to schedule a blood test every week for the first 8 weeks and monthly thereafter to monitor blood counts while taking REVLIMID
$\hfill\square$ Not sharing REVLIMID capsules with anyone—especially with females who can get pregnant
☐ Not donating blood while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID

☐ Instructions on REVLIMID dose and administration
Milligram (mg) Strength Number of Capsules Dispensed
FEMALE CHILDREN (<18 YEARS OF AGE):
☐ Parent or legal guardian must have read the REVLIMID REMS TM education material and agreed to ensure compliance
☐ Parent or legal guardian must inform the child's doctor when the child begins menses
Checklist for male patients ☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription
I COUNSELED ADULTS AND CHILDREN ON:
☐ Potential embryo-fetal toxicity and contraception (wearing a latex or synthetic condom every time when engaging in sexual intercourse with a female who can get pregnant)
\square Female partners of males taking REVLIMID $^{\otimes}$ (lenalidomide) must call their healthcare provider right away if they get pregnant
☐ Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism as well as risk of myocardial infarction and stroke
☐ The need for del 5q MDS patients to schedule a blood test every week for the first 8 weeks and monthly thereafter to monitor blood counts while taking REVLIMID
☐ Not sharing REVLIMID capsules with anyone—especially with females who can get pregnant
□ Not donating blood or sperm while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID
☐ Not breaking, chewing, or opening REVLIMID capsules
☐ Instructions on REVLIMID dose and administration
Milligram (mg) Strength Numbers of Capsules Dispensed
MALE CHILDREN (<18 YEARS OF AGE):
☐ Parent or legal guardian must have read the REVLIMID REMS TM education material and agreed to ensure compliance

All boxes and spaces must be marked or filled in during counseling with the patient for every prescription.	
Counselor Signature: Date:	
For more information about REVLIMID and the REVLIMID REMS TM program, please visit	t
www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at 1-888-4 5436. Celgene Corporation 86 Morris Ave Summit, NJ 07901	23.
REVLIMID is only available under a restricted distribution program, REVLIMID REMS $^{\mbox{\tiny TM}}.$	
Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.	
$((Celgene\ logo)) \qquad ((REVLIMID\ REMS^{TM}\ logo)) \qquad ((REVLIMID\ logo))$	
$REVLIMID^{@}\ is\ a\ registered\ trademark\ of\ Celgene\ Corporation.\ REVLIMID\ REMS^{TM}\ is\ a\ trademark\ of\ Celgene\ Corporation$	on.
© 2014 Celgene Corporation 6/14 REMS-REV14437	

REVLIMID REMSTM Pharmacy Certification Quiz

- 1. Authorization numbers for females of reproductive potential are valid for up to _____ days: (Mandatory Question)
 - a. **7 days**
 - b. 10 days
 - c. 14 days
 - d. 28 days
- 2. It is not necessary to obtain a confirmation number to dispense. (Mandatory Question)
 - a. True
 - b. False
- 3. Celgene REMS programs are mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacists on the serious risks and safe-use conditions for each treatment. (*Mandatory Question*)
 - a. **True**
 - b. False
- 4. It is not required to retain the prescription with the authorization and confirmation numbers for each filled prescription. It is not necessary to complete the Education and Counseling Checklist.
 - a. True
 - b. False
- 5. According to the package insert's boxed warnings and warnings and precautions, neutropenia, thrombocytopenia, deep venous thrombosis, and pulmonary embolism as well as risk of myocardial infarction and stroke have been reported in patients receiving REVLIMID. (Mandatory Question)
 - a. True
 - b. False
- 6. REVLIMID can cause serious birth defects. (Mandatory Question)
 - a. True
 - b. False
- 7. What pregnancy precautions are required for a female of reproductive potential with respect to heterosexual sexual contact?
 - a. Must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time she has sex with a male, beginning at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks after stopping therapy
 - b. Abstain from having any heterosexual sexual contact only while taking therapy
 - c. After stopping therapy it is okay to get pregnant at any time
 - d. Use 2 forms of birth control 2 weeks before taking therapy

- 8. What precautions are required for a male with respect to sexual contact with his female partner of reproductive potential?
 - a. Use of a latex or synthetic condom every time he has sexual intercourse with a FRP during therapy (including dose interruptions) and for 4 weeks after stopping therapy, even if he has undergone a successful vasectomy
 - b. Abstain from having any sexual contact with a female of reproductive potential only while taking therapy
 - c. Use latex or synthetic condoms while taking therapy. No precautions are necessary once treatment has stopped
 - d. Males taking therapy who have had a vasectomy do not need to use latex or synthetic condoms
- 9. For all Celgene REMS programs, female patients of reproductive potential must have a negative pregnancy test: (Mandatory Question)
 - a. Prior to initial prescription
 - b. Prior to subsequent prescription
 - c. Prior to initial prescription and prior to subsequent prescription
 - d. None of these
- 10. Adverse drug experiences that are suspected to be associated with the use of therapy, and any suspected pregnancy occurring during treatment, must be reported to Celgene. (Mandatory Question) a. True

 - b. False
- 11. The Medication Guide must be provided every time REVLIMID is dispensed. (Mandatory Question)
 - a. True
 - b. False
- 12. A certified Celgene REMS pharmacy cannot dispense more than a _____ supply of REVLIMID.
 - a. **28 day**
 - b. 3 month
 - c. 2 week
 - d. 1 year
- 13. Authorization numbers for patient risk categories other than females of reproductive potential are valid for up to _____ days. (Mandatory Question)
 - a. **30 days**
 - b. 10 days
 - c. 7 days
 - d. 28 days
- 14. A male patient can donate sperm at any time during therapy.
 - a. True

b. False

6/14 REMS-REV14398

$((REVLIMID REMS^{TM} logo))$

Patient Resource Pack REVLIMID Risk Evaluation and Mitigation Strategy (REMS)TM program (formerly known as the RevAssist[®] program)

The Patient Resource Pack contains:

- Patient Guide to the REVLIMID REMSTM Program
- Emergency Contraception Brochure
- Medication Guide

REVLIMID is only available under a restricted distribution program, REVLIMID REMS $^{\rm TM}$.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.

((Celgene logo)) ((REVLIMID logo))

REVLIMID $^{\otimes}$ is a registered trademark of Celgene Corporation. REVLIMID REMS $^{\text{TM}}$ is a trademark of Celgene Corporation.

©2013 Celgene Corporation 1/13 REMS-REV12104

Patient Guide to ((REVLIMID REMSTM logo))

Risk Evaluation And Mitigation Strategy (REMS)TM Program

This guide provides you important information about:

- The risks of REVLIMID[®] (lenalidomide)
 - o Birth defects (deformed babies) or death of an unborn baby
 - o Low white blood cells (neutropenia) and low platelets (thrombocytopenia)
 - o Blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism). To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine
- The REVLIMID REMSTM Program
 - o What females who can get pregnant need to know:
 - Birth control options
 - O What females who can not get pregnant need to know
 - o What males need to know

((REVLIMID logo))

Table of contents

Risks of REVLIMID® (lenalidomide)	4
What is the REVLIMID REMS TM program?	4
What do all patients need to know about the REVLIMID REMS TM program?	5
What do females who can get pregnant need to know about the REVLIMID REMS TM program?	6
What do females who can not get pregnant need to know about the REVLIMID REMS TM program?	. 12
What do males need to know about the REVLIMID REMS TM program?	. 14
Mandatory confidential patient surveys	16
Warning to natients taking REVI IMID	18

Risks of REVLIMID® (lenalidomide)

REVLIMID is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If REVLIMID is used during pregnancy, it can cause birth defects or death to unborn babies. REVLIMID must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking REVLIMID.

REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.

REVLIMID causes a higher chance for blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis) and lungs (pulmonary embolism). To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine.

What is the REVLIMID REMSTM program?

To avoid serious risks to unborn babies, REVLIMID is only available under a restricted distribution program called the "REVLIMID Risk Evaluation and Mitigation Strategy (REMS)TM" (formerly known as the RevAssist[®] program). Only certified prescribers can prescribe REVLIMID and only certified pharmacies can dispense REVLIMID. In order to receive REVLIMID, patients must be enrolled in the REVLIMID REMSTM program and agree to follow the requirements.

For more information about REVLIMID and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center toll-free at **1-888-423-5436.**

What do all patients need to know about the REVLIMID REMS $^{\mathrm{TM}}$ program?

General guidelines

- This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects
- REVLIMID[®] (lenalidomide) must be kept out of the reach of children
- Do not open or unnecessarily handle REVLIMID capsules
- Keep REVLIMID in a cool, dry place
- Do **not** donate blood while you are taking REVLIMID, during breaks (dose interruptions), and for 4 weeks after stopping REVLIMID
- Unused REVLIMID capsules should be returned for disposal to Celgene by calling
 1-888-423-5436 or to your REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to you

What do females who can get pregnant need to know about the REVLIMID REMSTM program?

A. Before taking REVLIMID® (lenalidomide)

- You must sign the REVLIMID® (lenalidomide) Patient-Physician Agreement Form that says you understand that REVLIMID should not be used during pregnancy, and that you agree not to become pregnant while taking REVLIMID
- If there is **any** chance that you can get pregnant, you must agree to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male starting at least 4 weeks **before** taking REVLIMID
- Your healthcare provider must give you a pregnancy test 10 to 14 days before you receive your first prescription for REVLIMID, and again within 24 hours before you receive your first prescription for REVLIMID. If you are pregnant, you cannot take REVLIMID
- You will have pregnancy tests before starting REVLIMID and while taking REVLIMID, even if you agree not to have sex with a male
- Before your healthcare provider can write your prescription for REVLIMID, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies
- Before dispensing REVLIMID[®] (lenalidomide), your REVLIMID REMSTM certified pharmacy will contact you to discuss treatment
- Your healthcare provider will talk with you about your birth control options
- 1. Choose at least 1 highly effective method and at least 1 additional effective method of birth control. Talk to your healthcare provider about the following acceptable birth control methods. See below.

Reliable Methods of Birth Control to Use Together

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD) Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants) Tubal ligation (having your tubes tied) Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	Male latex or synthetic condom Diaphragm Cervical cap

2. Use the 2 methods of birth control at the same time

• **Remember:** You must use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male. However, your healthcare provider may recommend that you use 2 different methods instead for medical reasons

What do females who can get pregnant need to know about the REVLIMID REMSTM program? (continued)

- Talk to your healthcare provider to make sure that other medicines or dietary supplements you are taking do not interfere with your hormonal birth control methods
- Remember, not having sex is the only birth control method that is 100% effective

3. Unacceptable methods of birth control

- Progesterone-only "mini-pills"
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield*

4. Take pregnancy tests

• You must have a pregnancy test performed by your healthcare provider 10 to 14 days before receiving your first prescription for REVLIMID[®] (lenalidomide) and again within 24 hours before receiving your first prescription for REVLIMID. Both pregnancy tests must have a negative result

^{*}A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

B. While taking REVLIMID® (lenalidomide)

- If you are able to get pregnant, you must continue (including during breaks [dose interruptions]) to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male
- Remember, not having sex is the only birth control method that is 100% effective
- You must talk to your healthcare provider before changing any birth control methods you have already agreed to use
- You will have a pregnancy test performed by your healthcare provider:
 - o Every week during the first 4 weeks of treatment, then
 - o Every 4 weeks if your menstrual cycles are regular, or
 - o Every 2 weeks if your cycles are irregular
 - o If you miss your period or have unusual menstrual bleeding, or
 - o If your medication is not dispensed within 7 days of taking the pregnancy test
- If you had sex with a male without using birth control, stop taking REVLIMID immediately and call your healthcare provider right away

What do females who can get pregnant need to know about the REVLIMID REMSTM program? (continued)

- If you get pregnant, or think you may be pregnant, you must **immediately** stop taking REVLIMID[®] (lenalidomide). Contact your healthcare provider immediately to discuss your pregnancy. If you do not have an obstetrician, your healthcare provider will refer you to one for care and counseling. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must not breastfeed a baby while you are taking REVLIMID
- In order to continue receiving REVLIMID, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your REVLIMID REMS™ healthcare provider. To take the survey, please go to www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at 1-888-423-5436

C. After you have stopped taking $REVLIMID^{\circledast}$ (lenalidomide)

- You must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male:
 - o For at least 4 weeks after stopping REVLIMID, or
 - o Do not have any sex with a male for 4 weeks after stopping REVLIMID

See also "General guidelines" on page 5 for requirements for all patients.

What do females who can not get pregnant need to know about the REVLIMID REMSTM program?

A. Before taking REVLIMID® (lenalidomide)

- You must sign the REVLIMID[®] (lenalidomide) Patient-Physician Agreement Form that says you are currently not pregnant and are not able to get pregnant. This means that:
 - o You have been in natural menopause for at least 2 years, or
 - You have had both ovaries and/or uterus removed
- For females who have not started their period (menstruation) and are under the age of 18, a parent or legal guardian must sign the REVLIMID® (lenalidomide) Patient-Physician Agreement Form that says the patient is not pregnant, is not able to get pregnant, and/or will not be having sex with a male for at least 4 weeks before starting REVLIMID
- Before your healthcare provider can write your prescription for REVLIMID, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies
- Before dispensing REVLIMID[®] (lenalidomide), your REVLIMID REMSTM certified pharmacy will contact you to discuss treatment

B. While taking REVLIMID

• In order to continue receiving REVLIMID, you must take part in a mandatory confidential survey every six months. You must also continue to discuss your treatment with your REVLIMID REMS™ healthcare provider. To take the survey, please go to www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at 1-888-423-5436

See also "General guidelines" on page 5 for requirements for all patients.

What do males need to know about the REVLIMID REMSTM program?

• You must use a latex or synthetic condom, **every time** you have sex with a female who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)

A. Before taking REVLIMID® (lenalidomide)

- You must sign the REVLIMID[®] (lenalidomide) Patient-Physician Agreement Form. You must agree that while taking REVLIMID you will use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant
- Before dispensing REVLIMID, your REVLIMID REMSTM certified pharmacy will contact you to discuss treatment

B. While taking REVLIMID

- You must use a latex or synthetic condom, **every time** (including during breaks [dose interruptions]) you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- Remember, not having sex is the only birth control method that is 100% effective
- You must tell your healthcare provider right away if you have sex with a female without using a latex or synthetic condom, or if you think for any reason that your partner is or may be pregnant. If for some reason your healthcare provider is not available, you can also call **1-888-668-2528** for information on emergency contraception
- You must **not** donate sperm while taking REVLIMID[®] (lenalidomide) (including during breaks [dose interruptions])
- In order to continue receiving REVLIMID, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your REVLIMID REMS™ healthcare provider. To take the survey, please go to www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at 1-888-423-5436

C. After you have stopped taking REVLIMID

- For 4 weeks after receiving your last dose of REVLIMID, you must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- You must **not** donate sperm for 4 weeks after stopping REVLIMID

See also "General guidelines" on page 5 for requirements for all patients.

Mandatory confidential patient surveys

As a patient who is enrolled in the REVLIMID REMSTM program for REVLIMID[®] (lenalidomide), you will need to complete a brief mandatory confidential survey as outlined below.

Adult females who can get pregnant

- Initial survey before first prescription
- Monthly

Adult females who can not get pregnant

- Initial survey before first prescription
- Every six months

Female children

- Initial survey before first prescription
- Monthly

Males

- No initial survey
- Monthly

Mandatory confidential survey process

- When your healthcare provider tells you to take the survey, go to the patient Mandatory Confidential Survey section of www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at 1-888-423-5436
- Be prepared with your patient identification number
- After completing your survey, your healthcare provider will also complete a survey. Your healthcare provider will then receive authorization to write your prescription
- The prescription will be sent to a REVLIMID REMSTM certified pharmacy. The REVLIMID REMSTM certified pharmacy will contact you to discuss your REVLIMID[®] (lenalidomide) therapy. You will not receive your medication until you speak with the REVLIMID REMSTM certified pharmacy
- For more information, contact the Celgene Customer Care Center at 1-888-423-5436

Warning to patients taking REVLIMID® (lenalidomide)

Attention females:

Do **not** take REVLIMID if you are pregnant, if you are breastfeeding, or if you are able to get pregnant and are not using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male.

Attention males:

You must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm).

You must **not** donate sperm while taking REVLIMID, during breaks (dose interruptions), and for 4 weeks after stopping REVLIMID.

Attention all patients:

You must **not** donate blood while taking REVLIMID[®] (lenalidomide), during breaks (dose interruptions), and for 4 weeks after stopping REVLIMID.

This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects.

REVLIMID must be kept out of the reach of children. Return any unused REVLIMID capsules for disposal to Celgene by calling **1-888-423-5436**, or to your REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to you.

You may require regular blood tests during REVLIMID treatment. Consult with your healthcare provider.

[Back Cover]

For more information about REVLIMID[®] (lenalidomide) and the REVLIMID REMSTM program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation 86 Morris Ave Summit, NJ 07901

REVLIMID is only available under a restricted distribution program, REVLIMID REMSTM.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.

 $((Celgene\ logo)) \qquad \qquad ((REVLIMID\ REMS^{TM}\ logo)) \qquad \qquad ((REVLIMID\ logo))$

REVLIMID $^{\otimes}$ is a registered trademark of Celgene Corporation. REVLIMID REMS $^{\text{TM}}$ is a trademark of Celgene Corporation.

© 2014 Celgene Corporation 6/14 REMS-REV14427

Patient Survey Reminder Card

Celgene logo

REMS Patient Survey Reminder

Patient Name	Date Survey Available
Doctor Office Contact and Phone #	

Product

Pharmacy Name_

Telephone Survey

Website Survey OR

From a touchtone phone dial 1-888-423-5436

Access the internet and type in the website address

www.CelgeneRiskManagement.com You are not required to have a User Name or



Press

Para español, oprime el numero dos

Password to complete a survey. To take your survey, left click your mouse on the button



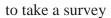
Patient Surveys



to identify that you are a patient

You will be asked for the following information. Please enter the information exactly as it was provided during your enrollment process









identification number (the number you provided during the enrollment process – for example your Social Security Number).

From the menu provided, select the drug that you have been prescribed.

After entering the information above, click







Enter your 9-digit patient







Start Survey

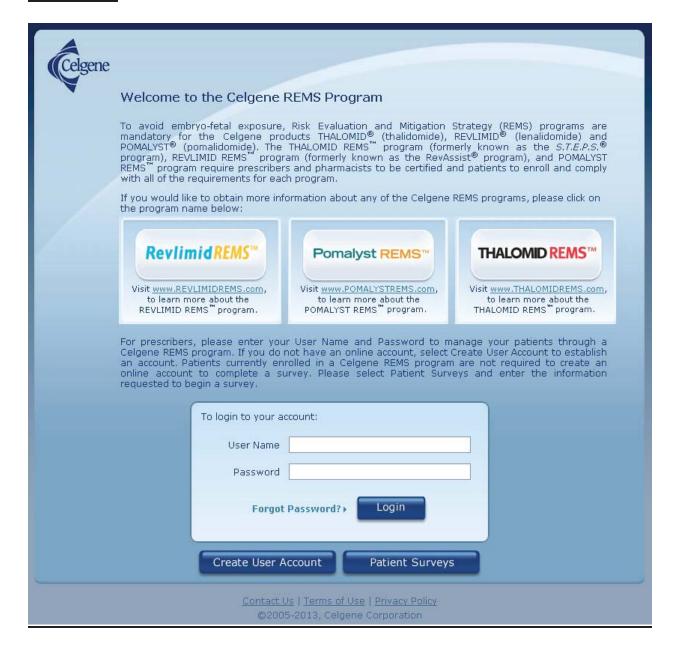
Your survey will then begin. Please answer all of the questions. Confirmation that the survey has been completed will be provided at the end of your survey.

Survey questions will be displayed 1 per page. Please be sure to complete the survey in its entirety. A summary page displaying your survey answers will be displayed at the end of your survey. Upon completion, send the survey to Celgene by clicking

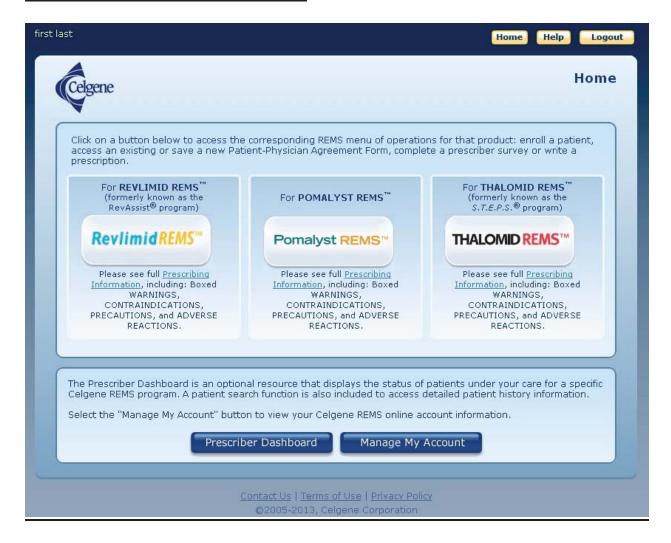
Send to Celgene

CelgeneRiskManagement.com

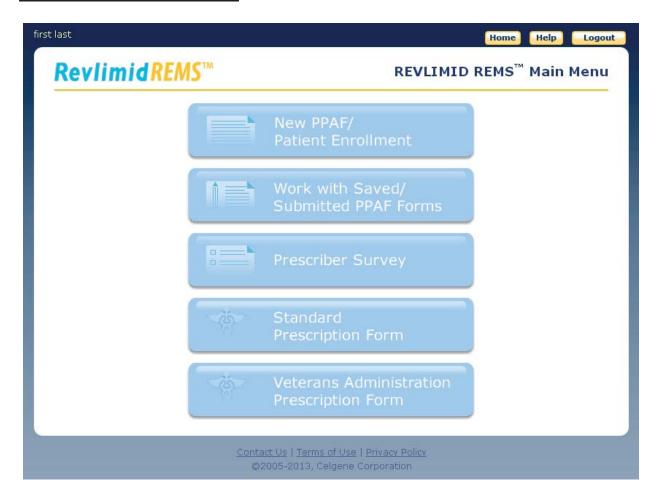
Login Page



Home Page (after prescriber logon)



REVLIMID REMS module



www. REVLIMIDREMS.com Web site



REVLIMID® is a registered trademark of Celgene Corporation. REVLIMID REMS™ is a trademark of Celgene Corporation. ©2013 year of origin. Celgene Corporation, www.celgene.com. This website is intended for residents of the United States only.



Revlimid REMS™





About the REVLIMID REMS™ program

REVLIMID® (lenalidomide) in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy.

REVLIMID is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called "REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ (formerly known as the RevAssist* program). Only certified prescribers can prescribe REVLIMID and only certified pharmacies can dispense REVLIMID in the REVLIMID REMS™ program.

In order to receive REVLIMID, all patients must be enrolled in the REVLIMID REMS $^{\text{TM}}$ program and agree to comply with the requirements of the REVLIMID REMS $^{\text{TM}}$ program.

Key points of the REVLIMID REMS™ program

rescriber

- The prescriber enrolls and becomes certified with Celgene for the REVLIMID REMS™ program
- · The prescriber counsels patient on benefits and risks of REVLIMID
- · The prescriber provides contraception and emergency contraception counseling
- · The prescriber verifies negative pregnancy test for all female patients of reproductive potential
- The prescriber completes a REVLIMID® (lenalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
- · The prescriber/patient completes applicable mandatory confidential survey
- The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category
- . The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- · The prescriber sends REVLIMID prescription to certified pharmacy

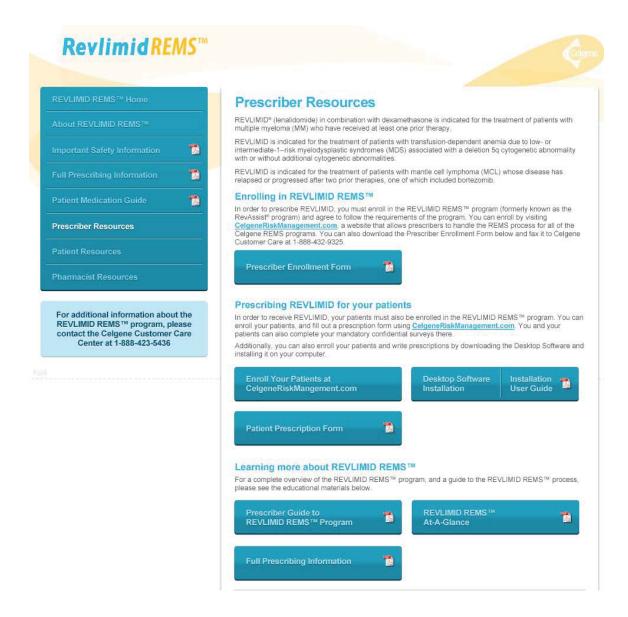
Pharmacy

- The pharmacy certifies with Celgene for the REVLIMID REMS™ program
- · The certified pharmacy must obtain a confirmation number from Celgene before dispensing
- The certified pharmacy counsels the patient, and completes an Education and Counseling Checklist
- The certified pharmacy dispenses REVLIMID to patient along with a Medication Guide

Privacy policy | Terms of Use | Site map | Contact us

REVLIMID* is a registered trademark of Celgene Corporation. REVLIMID REMS** is a trademark of Celgene Corporation. @2013 year of origin. Celgene Corporation, www.celgene.com. This website is intended for residents of the United States only.





Please report adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID to Celgene using any of the following methods:

REPORTING TO CELGENE

Email: drugsafety@celgene.com

Telephone: 1-908-673-9667

Toll-free: 1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Ceigene Customer Care Center)

Mail to: Global Drug Safety & Risk Management Cetgene Corporation 300 Connell Dr. Suite 6000

Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm

Telephone: 1-800-332-1088

1-800-332-0178 Fax: Mail to: MedWatch

5600 Fishers Lane Rockville, MD 20852-9787

Privacy policy | Terms of Use | Site map | Contact us

REVLIMID[®] is a registered trademark of Celgene Corporation. REVLIMID REMS™ is a trademark of Celgene Corporation. ©2013 year of origin. Celgene Corporation, www.celgene.com. This website is intended for residents of the United States only.









The Celgene REMS Pharmacy Portal

In addition to calling the Celgene Customer Care Center to obtain a confirmation number for a prescription, eligible pharmacies can obtain confirmation numbers using the Celgene REMS Pharmacy Portal at CelgeneREMSPharmacyPortal.com. Contact your Celgene Account Manager to see if your pharmacy is eligible.

Celgene REMS Pharmacy Portal

Please report adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID to Celgene using any of the following methods:

REPORTING TO CELGENE

Email: drugsafety@celgene.com

Telephone: 1-908-673-9667

Toll-free: 1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Ceigene Customer Care Center)

1-908-673-9115 Fax:

Mail to:

Global Drug Safety & Risk Management Celgene Corporation

300 Connell Dr. Suite 6000

Berkeley Heights, NJ 07922

Adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm

Telephone: 1-800-332-1088 1-800-332-0178 Fax: Mail to: MedWatch

5600 Fishers Lane Rockville, MD 20852-9787

Privacy policy | Terms of Use | Site map | Contact us

REVLIMID® is a registered trademark of Celgene Corporation. REVLIMID REMS™ is a trademark of Celgene Corporation. ©2013 year of origin. Celgene Corporation, www.celgene.com. This website is intended for residents of the United States only.





Prescriber Guide to Revlimid REMS™

Risk Evaluation and Mitigation Strategy (REMS)™ Program

Due to its structural similarity to thalidomide, a known teratogen, REVLIMID[®] (lenalidomide) is approved for marketing only under a restricted distribution program approved by the Food and Drug Administration. This program is called the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)[™] program (formerly known as the RevAssist[®] program).

This guide contains important information for prescribers about:

- The risks of REVLIMID, including a boxed warning for
 - Embryo-fetal toxicity
 - Hematologic toxicity
 - Venous and arterial thromboembolism
- The REVLIMID REMS™ program
 - Prescriber Certification
 - Patient Enrollment
 - Contraceptive Requirements and Counseling for Patients
 - Initial and Subsequent Prescription Requirements

REVLIMID REMS™ Resources for Prescribers Include:

- Prescriber Guide to REVLIMID REMS™ Program
- CD-ROM, including Patient-Physician Agreement Form and Patient Prescription Form Software and Installation Instructions
- Full Prescribing Information for REVLIMID



Table of contents

About REVLIMID® (lenalidomide)3
The REVLIMID REMS™ program4
Key points of the REVLIMID REMS TM program4
Patient enrollment into REVLIMID REMS TM program5
escription requirements7
All patients7
Female patients7
o Females of reproductive potential8
o Females not of reproductive potential10
Male patients10
Del 5q MDS patients10
Initial mandatory confidential survey11
Additional information for the prescriber11
Subsequent prescription requirements12
After the last dose of REVLIMID13
dering English and non-English materials14
Adverse drug experience reporting procedure for healthcare professionals15

About REVLIMID® (lenalidomide)

REVLIMID in combination with dexamethasone is indicated for the tr multiple myeloma (MM) who have ${\bf r}$

REVLIMID is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndr

cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

Risks of REVLIMID

REVLIMID has a Boxed Warning for embryo-fetal toxicity deep venous thrombosis (DVT) and pulmonary embolism (PE) as well as risk of myocardial infarction and stroke.

Due to its structural similarity to thalidomide, a known teratogen is contraindicated in pregnant females or females capable of becoming pr

Females of reproductive potential may be tr

precautions to avoid pregnancy.

REVLIMID is associated with signifi

patients with del 5q MDS. Many patients taking REVLIMID may r

and/or reduction. Evaluate your del 5q MDS patients closely for cytopenias. Patients on

REVLIMID should have their complete blood counts monitor

8 weeks of therapy, and at least monthly ther

There is a significant risk of deep venous thr

well as risk of myocardial infarction and str

plus dexamethasone in combination. Monitor for and advise patients about signs and symptoms of thromboembolism. Advise patients to seek immediate medical car

they develop symptoms such as shortness of br

Thromboprophylaxis is recommended and the choice of r

assessment of the patient's underlying risks.

The REVLIMID REMSTM program

avoid embryo-fetal exposure, REVLIMID® (lenalidomide) is only available under a restricted distribution program called "REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™." Only certified prescribers can prescribe REVLIMID and only certified pharmacies can dispense REVLIMID in the REVLIMID REMS[™] program.

der to receive REVLIMID, all patients must be enrolled in REVLIMID REMSTM and agree to comply with the requirements of the REVLIMID REMSTM program. Information about REVLIMID and the REVLIMID REMSTM program can be obtained by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center toll-free at 1-888-423-5436.

Key points of the REVLIMID REMS" program

Prescriber

escriber enrolls and becomes certified with Celgene for the REVLIMID REMSTM program escriber counsels patient on benefits and risks of REVLIMID escriber provides contraception and emergency contraception counseling

escriber provides contradeption and entergency contradeption con escriber verifies negative pregnancy test for all female patients of oductive potential

escriber completes a $\mathsf{REVLIMID}^{\otimes}$ (lenalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene

escriber/patient completes applicable mandatory confidential survey escriber obtains an authorization number from Celgene and writes it on every escription, along with the patient risk category

escriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions

escriber sends REVLIMID prescription to certified pharmacy

harmacy

The pharmacy certifies with Celgene for REVLIMID REMS™

The certified pharmacy must obtain a confirmation number from Celgene before dispensing The certified pharmacy dispenses REVLIMID to patient along with a Medication Guide

REVLIMID REMSTM patient enrollment

- Obtain, review, and complete the REVLIMID Form online at www.CelgeneRiskManagement.com calling the Celgene Customer Car
- Prescribers who do not have access to a computer compatible with the software, will be pr
 For additional assistance, please contact the Celgene Customer Car Hematology Oncology Consultant
- Patient, parent/legal guardian, and/or authorized r (lenalidomide) Patient-Physician Agr

Help Ensure Timely Processing of Each Prescription

Fill Out Form as Directed

- Write only in the designated areas on the REVLIMID Agreement Form
- \bullet The box next to each statement must be marked (with an "X") to indicate understanding
- The form must be completed and signed by both pr

Instructions for Female Patients

For female patients, the prescriber will need to pr
 been in surgical menopause, chemical menopause, or natural menopause for at least 24 months

Instructions for Minors

 If the patient is under 18 years of age, his or her legal guar mark the statement in each block of the form (with an "X"), and agr by signing and dating the form

Instructions for Incompetent Adult Patients

For an incompetent adult patient, an authorized r REVLIMID® (lenalidomide) Patient-Physician Agr

REVLIMID REMS" patient enrollment (continued)

An authorized representative is a caretaker authorized under applicable state law to consent eatment on the incompetent patient's behalf

The authorized representative must read the material, mark the statements, and agree to e compliance by signing and dating the form

If the authorized representative does not have the power of attorney, a signed and dated letter from the prescriber, on the prescriber's letterhead, must be submitted to the Celgene Customer Care Center, along with the REVLIMID® (lenalidomide)

Patient-Physician Agreement Form. This letter must contain the following: a statement that the incompetent patient lacks the capacity to complete the REVLIMID® (lenalidomide)

Patient-Physician Agreement Form, including identification of the medical condition causing the incapacity; the name and address of the authorized representative; the authorized

esentative's relationship to the patient; and an opinion that the authorized representative accepts responsibility for the patient's compliance with the REVLIMID REMSTM program and is authorized to consent to treatment with REVLIMID on behalf of the patient

Send in Completed Forms

Send the completed REVLIMID® (lenalidomide) Patient-Physician Agreement Form online www.CelgeneRiskManagement.com, or to the Celgene Customer Care Center by faxing to 1-888-432-9325

ou will receive confirmation electronically or via fax to your office once the patient

Once REVLIMID® (lenalidomide) Patient-Physician Agreement Form is received, both female patients and prescriber can take their surveys as required. Male patients do not take initial surveys

In the event that you do not receive this confirmation within 15 minutes, call the Celgene Customer Care Center

If therapy with REVLIMID is discontinued for 12 consecutive months, the patient must oll again in the REVLIMID REMSTM program. Follow the above procedures to re-enroll the patient.

Initial prescription requirements

ALL PATIENTS

- Provide comprehensive counseling on the benefi REVLIMID® (lenalidomide)
- Patients must be counseled on the potential risks of birth defects, other side ef and important precautions associated with REVLIMID
- Provide counseling not to share REVLIMID capsules, and not to donate blood during treatment (including dose interruptions) and for 4 weeks after r of REVLIMID, as well as counseling on appr emergency contraception
- Provide patients with education materials pr Resource Pack
- nesource rack

 Patients should be instructed to not extensively handle or open REVLIMID capsules
- Instruct patients to return unused REVLIMID capsules for disposal to Celgene or to their REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to them

FEMALE PATIENTS

Determine if female patient is of r

Two categories:

1. Females of Reproductive Potential

- All females who are menstruating, amenorrheic fr 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category
- 2. Females Not of Reproductive Potential
- Females who have been in natural menopause for at least 24 consecutive months, or who have had a hysterectomy and/or bilateral oophor have not started menstruating

Initial prescription requirements (continued)

1. Females of Reproductive Potential

egnancy test requirements

Obtain a negative pregnancy test 10 to 14 days prior to writing an initial prescription escription for REVLIMID even if continuous abstinence is the chosen method of for REVLIMID $^{\! \odot}$ (lenalidomide) and again within 24 hours prior to writing an initial birth control

- The pregnancy test must be sensitive to at least 50 mIU/mL
- Pregnancy testing should occur weekly during the first 4 weeks of use
- Pregnancy testing should be repeated every 4 weeks if patient has regular menses or is amenorrheic, or every 2 weeks if irregular menses
- If a patient misses her period or if there is any abnormality in menstrual bleeding, REVLIMID should be discontinued immediately. Obtain a pregnancy test and counsel the patient

egnancy does occur during treatment, REVLIMID must be immediately

discontinued. Any suspected embryo-fetal exposure to REVLIMID must be reported to the Celgene Customer Care Center at 1-888-423-5436. The patient should be immediately to the FDA via the MedWatch number at 1-800-FDA-1088 and also eferred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling

The patient must not breastfeed a baby while being treated with REVLIMID

Initial prescription requirements (continued)

Patient Counseling on Contraception Requir

Contraception requirements

- Female patients of reproductive potential must either completely abstain fr heterosexual sexual contact or must use 2 methods of r
- Reliable contraceptive methods include using at the same time at least 1 highly effective method and at least 1 additional method of birth contr have sex with a male
- Reliable contraceptive methods must be started at least 4 weeks befor for at least 4 weeks following discontinuation of therapy REVLIMID® (lenalidomide) therapy

Effective Methods of Birth Contr

Highly effective birth control methods

- Intrauterine device (IUD)
- hormonal patches, injections, vaginal rings, or implants) Hormonal methods (birth control pills,
- Tubal ligation (having your tubes tied)
- Partner's vasectomy (tying of the tubes to prevent the passing of sperm)

Remind all patients that not having any sexual inter method that is 100% effective.

- Unacceptable forms of contraception:
- 0 0 Progesterone-only "mini-pills" IUD Progesterone T

 - Female condoms
 Natural family planning (rhythm method)
- or breastfeeding
- Patients should be counseled that concomitant use of certain pr dietary supplements can decrease the ef
- IUD contraception is medically contraindicated, 2 other contraceptive methods may be used simultaneously during periods of concomitant use and for 4 weeks after

*A cervical shield should not be confused with a cervical cap, which is an ef

Initial prescription requirements (continued)

2. Females Not of Reproductive Potential

The patient must confirm that she is currently not pregnant, nor of reproductive potential as she has been in natural menopause for at least 24 months, or had a hysterectomy and/or bilateral oophorectomy

The parent or guardian must confirm that a prepubertal female child is not now egnant, nor is of reproductive potential as **menstruation has not yet begun**, and/or the child will not be engaging in heterosexual sexual contact for at least 4 weeks before REVLIMID® (lenalidomide) therapy, during therapy, and for at least 4 weeks after stopping therapy

MALE PATIENTS

Male patients must be instructed to use a latex or synthetic condom every time they have intercourse with a female of reproductive potential, even if they have undergone a successful vasectomy. The risk to the developing baby from the semen of male patients REVLIMID therapy is unknown

Male patients must be instructed not to donate sperm during treatment (including dose interruptions) and for 4 weeks after their last dose of REVLIMID

Del 5q MDS PATIENTS

Evaluate your del 5q MDS patients closely for cytopenias. Obtain a weekly CBC for the first 8 weeks of treatment, and at least monthly thereafter

Initial mandatory confidential

Females

 Instruct the female patient to complete a brief initial mandatory confi www.CelgeneRiskManagement.com subsequent prescription requirements

Males

Males do not need to take the initial survey

Prescribers

- Prescriber will complete a brief mandatory confi www.CelgeneRiskManagement.com at 1-888-423-5436, for every patient to enter some of the following information:
- o Prescriber's identification number
 - o Patient's identification number
- Date and result of patient's pr from date of last pregnancy test
 - Average daily dose
- Total number of days supply (cannot exceed 28 days)
- An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the pr are valid for 7 days from date of and 30 days from the date it is issued for all other patients. No automatic r telephone prescriptions are permitted

ADDITIONAL INFORMATION FOR THE PRESCRIBER

- Healthcare provider must send the pr
 To locate a certified pharmacy, please visit
- Prescribe no more than 4 weeks (28 days) of therapy

Subsequent prescription requirements

escriber must complete a brief mandatory confidential survey to obtain a new authorization number **every time** a prescription for REVLIMID® (lenalidomide) is written. No automatic refills or telephone prescriptions are permitted. The patient risk category must be written on the prescription.

FEMALE PATIENTS

ovide counseling as outlined in the "FEMALE PATIENTS" section on pages 7-10

Follow pregnancy test requirements as outlined in "Pregnancy test requirements" section on page 8 Female patients must complete a brief mandatory confidential survey according to the following schedule:

- Before prescription is obtained
- Monthly

Adult females of reproductive potential All female children

Every 6 months

Adult females not of reproductive potential

ATIENTS

ovide patient counseling as outlined in the "MALE PATIENTS" section on page 10

Male patients must complete a brief mandatory confidential survey once a month

Males do not complete an initial survey

Del 5q MDS PATIENTS

Evaluate your del 5q MDS patients closely for cytopenias. Obtain a weekly CBC for rst 8 weeks of treatment and at least monthly thereafter

After the last dose of REVLIMID

After patients have stopped taking REVLIMID, they must do the following:

ALL PATIENTS

- Must not share REVLIMID capsules—especially with females of r
- Must return any unused REVLIMID capsules for disposal to Celgene or their REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to them
- Must not donate blood for 4 weeks after stopping REVLIMID

FEMALE PATIENTS

 Must not get pregnant for at least 4 weeks after stopping REVLIMID by using the appropriate contraceptives each time engaging in sexual activity with a male

MALE PATIENTS

- Must use a latex or synthetic condom for 4 weeks after stopping REVLIMID
- Must not donate sperm for 4 weeks after stopping REVLIMID

Ordering English and non-English materials

CALL CELGENE CUSTOMER CARE CENTER AT 1-888-423-5436

Materials are available in 16 languages and include:

- o REVLIMID® (lenalidomide) Patient-Physician Agreement Forms
- Patient Guide to REVLIMID REMS™ Program
- Mandatory confidential survey forms

	Portuguese Russian Spanish Vietnamese
	Japanese Korean Laotian Polish
guages:	French German Greek Italian
vailable languages:	Cambodian Chinese

REVLIMID® (lenalidomide) Patient-Physician Agreement Forms, Patient Guide to REVLIMID REMSTM Program, and mandatory confidential survey forms requested will be faxed directly to the number you indicate. Please be prepared to provide:

escriber's:

cation Number ess Fax Number

Patient's: Name

Name Full Address Phone Number Date of Birth Identification Number

Diagnosis (most recent version of ICD code)

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety thr experiences associated with the use of REVLIMID

Please report adverse drug experiences that ar REVLIMID and any suspected pregnancy occurring during the tr Celgene using any of the following methods.

REPORTING TO CELGENE

- Email: drugsafety@celgene.com
- Telephone: 1-908-673-9667
- Toll free: 1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Celgene Customer Car
- Fax: 1-908-673-9115
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the tr

be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online: https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
- Telephone: 1-800-FDA-1088
- Fax: 1-800-FDA-0178
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

For more information about REVLIMID® (lenalidomide) and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation 86 Morris Ave Summit, NJ 07901

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.



Revlimid REMS™



Patient Guide to Revlimid REMS™

Risk Evaluation and Mitigation Strategy (REMS)™ Program

This guide provides you important information about:

- The risks of REVLIMID® (lenalidomide)
 - Birth defects (deformed babies) or death of an unborn baby
 - Low white blood cells (neutropenia) and low platelets (thrombocytopenia)
 - Blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis), and lungs (pulmonary embolism). To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine
- The REVLIMID REMS[™] program
 - What females who can get pregnant need to know
 - Birth control options
 - What females who can not get pregnant need to know
 - What males need to know



Table of contents

Risks of REVLIMID® (lenalidomide)4
What is the REVLIMID REMS TM program?4
What do all patients need to know about the REVLIMID REMS $^{\scriptscriptstyleTM}$ program?5
What do females who can get pregnant need to know
about the REVLIMID REMS™ program?6
What do females who can not get pregnant need to know about the REVLIMID REMS™ program?12
What do males need to know
What do males need to know about the REVLIMID REMS™ program?14
Mandatory confidential patient surveys16
Warning to patients taking REVLIMID18



Risks of REVLIMID® (lenalidomide)

REVLIMID is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If REVLIMID is used during pregnancy, it can cause birth defects or death to unborn babies. REVLIMID must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking REVLIMID.

REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients.

REVLIMID causes a higher chance for blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis), and lungs (pulmonary embolism). To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine.

What is the REVLIMID REMS™ program?

To avoid serious risks to unborn babies, REVLIMID is only available under a restricted distribution program called the "REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™" (formerly known as the RevAssist® program). Only certified prescribers can prescribe REVLIMID and only certified pharmacies can dispense REVLIMID. In order to receive REVLIMID, patients must be enrolled in the REVLIMID REMS™ program and agree to follow the requirements.

For more information about REVLIMID and the REVLIMID REMS[™] program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center toll-free at **1-888-423-5436**.

What do all patients need to know about the REVLIMID REMS™ program?

General guidelines

- This medicine is only for you. Do not share it with anyone even if they have symptoms like yours. It may harm them and can cause birth defects
- REVLIMID® (lenalidomide) must be kept out of the reach of children
- Do not open or unnecessarily handle REVLIMID capsules
- Keep REVLIMID in a cool, dry place
- Do **not** donate blood while you are taking REVLIMID, during breaks (dose interruptions), and for 4 weeks after stopping REVLIMID
- Unused REVLIMID capsules should be returned for disposal to Celgene by calling 1-888-423-5436, or to your REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to you

What do females who can get pregnant need to know about the REVLIMID REMS™ program?

A. Before taking REVLIMID® (lenalidomide)

- You must sign the REVLIMID® (lenalidomide)
 Patient-Physician Agreement Form that says you
 understand that REVLIMID should not be used
 during pregnancy, and that you agree not to
 become pregnant while taking REVLIMID
- If there is any chance that you can get pregnant, you must agree to use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time you have sex with a male starting at least 4 weeks before taking REVLIMID
- Your healthcare provider must give you a pregnancy test 10 to 14 days before you receive your first prescription for REVLIMID, and again within 24 hours before you receive your first prescription for REVLIMID. If you are pregnant, you cannot take REVLIMID
- You will have pregnancy tests before starting REVLIMID and while taking REVLIMID, even if you agree not to have sex with a male
- Before your healthcare provider can write your prescription for REVLIMID, you must take part in a mandatory confidential survey. The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies

- Before dispensing REVLIMID® (lenalidomide), your REVLIMID REMS™ certified pharmacy will contact you to discuss treatment
- Your healthcare provider will talk with you about your birth control options
- Choose at least 1 highly effective method and at least 1 additional effective method of birth control. Talk to your healthcare provider about the following acceptable birth control methods. See below.

Reliable Methods of Birth Control to Use Together

Highly effective birth control methods	Additional effective birth control methods
Intrauterine device (IUD)	
Hormonal methods (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Male latex or synthetic condom
Tubal ligation (having your	Diaphragm
tubes tied)	Cervical cap
Partner's vasectomy (tying of the tubes to prevent the passing of sperm)	

2. Use the 2 methods of birth control at the same time

Remember: You must use at the same time
 at least 1 highly effective method and at least
 1 additional effective method of birth control
 every time you have sex with a male. However,
 your healthcare provider may recommend that
 you use 2 different methods instead for
 medical reasons

What do females who can get pregnant need to know about the REVLIMID REMS™ program? (continued)

- Talk to your healthcare provider to make sure that other medicines or dietary supplements you are taking do not interfere with your hormonal birth control methods
- Remember, not having sex is the only method of birth control that is 100% effective

3. Unacceptable methods of birth control

- Progesterone-only "mini-pills"
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield*

4. Take pregnancy tests

 You must have a pregnancy test performed by your healthcare provider 10 to 14 days before receiving your first prescription for REVLIMID® (lenalidomide) and again within 24 hours before receiving your first prescription for REVLIMID. Both pregnancy tests must have a negative result

B. While taking REVLIMID® (lenalidomide)

- If you are able to get pregnant, you must continue (including during breaks [dose interruptions]) to use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time you have sex with a male
- Remember, not having sex is the only method of birth control that is 100% effective
- You must talk to your healthcare provider before changing any birth control methods you have already agreed to use
- You will have a pregnancy test performed by your healthcare provider:
 - Every week during the first 4 weeks of treatment, then
 - Every 4 weeks if your menstrual cycles are regular, or
 - Every 2 weeks if your cycles are irregular
 - If you miss your period or have unusual menstrual bleeding, or
 - If your medication is not dispensed within7 days of taking the pregnancy test
- If you had sex with a male without using birth control, stop taking REVLIMID immediately and call your healthcare provider right away

9

^{*}A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

What do females who can get pregnant need to know about the REVLIMID REMS™ program? (continued)

- If you get pregnant, or think you may be pregnant, you must immediately stop taking REVLIMID® (lenalidomide). Contact your healthcare provider immediately to discuss your pregnancy. If you do not have an obstetrician, your healthcare provider will refer you to one for care and counseling. If for some reason your healthcare provider is not available, you can also call 1-888-668-2528 for information on emergency contraception
- You must not breastfeed a baby while you are taking REVLIMID
- In order to continue receiving REVLIMID, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your REVLIMID REMS™ healthcare provider. To take the survey, please go to www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at 1-888-423-5436

C. After you have stopped taking REVLIMID® (lenalidomide)

- You must continue to use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time you have sex with a male:
 - For at least 4 weeks after stopping REVLIMID, or
 - Do not have any sex with a male for 4 weeks after stopping REVLIMID

See also "General guidelines" on page 5 for requirements for all patients.

What do females who can not get pregnant need to know about the REVLIMID REMS™ program?

A. Before taking REVLIMID® (lenalidomide)

- You must sign the REVLIMID® (lenalidomide)
 Patient-Physician Agreement Form that says you are currently not pregnant and are not able to get pregnant. This means that:
 - You have been in natural menopause for at least 2 years, or
 - You have had both ovaries and/or uterus removed
- For females who have not started their period (menstruation) and are under the age of 18, a parent or legal guardian must sign the REVLIMID® (lenalidomide) Patient-Physician Agreement Form that says the patient is not pregnant, is not able to get pregnant, and/or will not be having sex with a male for at least 4 weeks before starting REVLIMID
- Before your healthcare provider can write your prescription for REVLIMID, you must take part in a mandatory confidential survey.
 The survey will make sure that you receive, understand, and can follow information designed to prevent serious risks to unborn babies

 Before dispensing REVLIMID® (lenalidomide), your REVLIMID REMS™ certified pharmacy will contact you to discuss treatment

B. While taking REVLIMID

 In order to continue receiving REVLIMID, you must take part in a mandatory confidential survey every six months. You must also continue to discuss your treatment with your REVLIMID REMS™ healthcare provider. To take the survey, please go to www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at 1-888-423-5436

See also "General guidelines" on page 5 for requirements for all patients.

What do males need to know about the REVLIMID REMS™ program?

 You must use a latex or synthetic condom, every time you have sex with a female who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)

A. Before taking REVLIMID® (lenalidomide)

- You must sign the REVLIMID® (lenalidomide)
 Patient-Physician Agreement Form. You must agree
 that while taking REVLIMID you will use a latex or
 synthetic condom every time you have sex with a
 female who is pregnant or who is able to get pregnant
- Before dispensing REVLIMID, your REVLIMID REMS™ certified pharmacy will contact you to discuss treatment

B. While taking REVLIMID

- You must use a latex or synthetic condom every time (including during breaks [dose interruptions]) you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm)
- Remember, not having sex is the only method of birth control that is 100% effective

- You must tell your healthcare provider right away
 if you have sex with a female without using a
 latex or synthetic condom, or if you think for any
 reason that your partner is or may be pregnant. If
 for some reason your healthcare provider is not
 available, you can also call 1-888-668-2528 for
 information on emergency contraception
- You must **not** donate sperm while taking REVLIMID[®] (lenalidomide) (including during breaks [dose interruptions])
- In order to continue receiving REVLIMID, you must take part in a mandatory confidential survey every month. You must also continue to discuss your treatment with your REVLIMID REMS™ healthcare provider. To take the survey, please go to www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at 1-888-423-5436

C. After you have stopped taking REVLIMID

- For 4 weeks after receiving your last dose
 of REVLIMID, you must use a latex or synthetic
 condom every time you have sex with a female
 who is pregnant or who is able to get pregnant,
 even if you have had a successful vasectomy (tying
 of the tubes to prevent the passing of sperm)
- You must **not** donate sperm for 4 weeks after stopping REVLIMID

See also "General guidelines" on page 5 for requirements for all patients.

Mandatory confidential patient surveys

As a patient who is enrolled in the REVLIMID REMS[™] program for REVLIMID[®] (lenalidomide), you will need to complete a brief mandatory confidential survey as outlined below.

Adult females who can get pregnant

- Initial survey before first prescription
- Monthly

Adult females who can not get pregnant

- Initial survey before first prescription
- Every six months

Female children

- Initial survey before first prescription
- Monthly

Males

- No initial survey
- Monthly

Mandatory confidential survey process

- When your healthcare provider tells you to take the survey, go to the patient Mandatory Confidential Survey section of www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at 1-888-423-5436
- Be prepared with your patient identification number
- After completing your survey, your healthcare provider will also complete a survey. Your healthcare provider will then receive authorization to write your prescription
- The prescription will be sent to a REVLIMID REMS[™] certified pharmacy. The REVLIMID REMS[™] certified pharmacy will contact you to discuss your REVLIMID[®] (lenalidomide) therapy. You will not receive your medication until you speak with the REVLIMID REMS[™] certified pharmacy
- For more information, contact the Celgene Customer Care Center at 1-888-423-5436

Warning to patients taking REVLIMID® (lenalidomide)

Attention females:

Do **not** take REVLIMID if you are pregnant, if you are breastfeeding, or if you are able to get pregnant and are not using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time** you have sex with a male.

Attention males:

You must use a latex or synthetic condom **every time** you have sex with a female who is pregnant or who is able to get pregnant, even if you have had a successful vasectomy (tying of the tubes to prevent the passing of sperm).

You must **not** donate sperm while taking REVLIMID, during breaks (dose interruptions), and for 4 weeks after stopping REVLIMID.

Attention all patients:

You must **not** donate blood while taking REVLIMID® (lenalidomide), during breaks (dose interruptions), and for 4 weeks after stopping REVLIMID.

This medicine is **only** for you. **Do not share it with anyone** even if they have symptoms like yours. It may harm them and can cause birth defects.

REVLIMID must be kept out of the reach of children. Return any unused REVLIMID capsules for disposal to Celgene by calling **1-888-423-5436**, or to your REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to you.

You may require regular blood tests during REVLIMID treatment. Consult with your healthcare provider.

For more information about REVLIMID® (lenalidomide) and the REVLIMID REMSTM program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation 86 Morris Ave Summit, NJ 07901

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.







REVLIMID® is a registered trademark of Celgene Corporation. REVLIMID REMS $^{\text{TM}}$ is a trademark of Celgene Corporation.

Celgene

REMS Patient Survey Reminder

Patient Name	Date Survey Available	
Doctor Office Contact and Phone #		
Product	Pharmacy Name	

Telephone Survey



From a touchtone phone dial

1-888-423-5436

Press



Para espanol, oprime el numero dos

Press



to identify that you are a patient

Press



to take a survey



Enter your 9-digit patient identification number (the number you provided during the enrollment process – for example your Social Security Number).

From the menu provided, select the drug that you have been prescribed.

Press



OR

Press 2

0R

Press 3

Your survey will then begin. Please answer all of the questions. Confirmation that the survey has been completed will be provided at the end of your survey.

Website Survey

Access the internet and type in the website address **www.CelgeneRiskManagement.com**

You are not required to have a User Name or Password to complete a survey. To take your survey, left click your mouse on the button

Patient Surveys

You will be asked for the following information. Please enter the information exactly as it was provided during your enrollment process

= Patient Last Nam	e:
" Patient First Nam	e:
* Patient Identification Number	
	Social Security Number e.g. 123456789

After entering the information above, click

Start Survey

Survey questions will be displayed 1 per page. Please be sure to complete the survey in its entirety. A summary page displaying your survey answers will be displayed at the end of your survey. Upon completion, send the survey to Celgene by clicking

Send to Celgene

Revlimid REMS™

Program for REVLIMID® (lenalidomide) Education and Prescribing Safety

Dear Prescriber:

Enclosed are your REVLIMID REMS™ program education materials.

Celgene Corporation is pleased to provide you with the enclosed materials for use in the REVLIMID REMS™ program (formerly known as the RevAssist® program).

Important Information about the REVLIMID REMS™ program

- To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called "REVLIMID REMS™"
- Lenalidomide is contraindicated in pregnant females and females capable of becoming pregnant.
 Females of reproductive potential may be treated with lenalidomide provided adequate precautions are taken to avoid pregnancy
- Male Patients: Clinical data has demonstrated the presence of lenalidomide in human semen. Male
 patients taking REVLIMID should not donate sperm. Males receiving REVLIMID must always use a
 latex or synthetic condom during any sexual contact with females of reproductive potential even if
 they have undergone a successful vasectomy
- Only prescribers and pharmacies certified with REVLIMID REMS[™] can prescribe and dispense REVLIMID to patients who are enrolled and meet all the conditions of the REVLIMID REMS[™] program

As a prescriber certified with the REVLIMID REMS[™] program, please review and familiarize yourself with the contents of the enclosed REVLIMID REMS[™] Kit:

Prescriber Materials

- REVLIMID REMS[™] software and Installation Guide
- Prescriber Guide to the REVLIMID REMS[™] Program
- REVLIMID Full Prescribing Information

Patient Materials (Patient Resource Pack)

- Patient Guide to REVLIMID REMS[™] Program
- Emergency Contraception Brochure
- MEDICATION GUIDE

To order additional Patient Resource Packs, or if you have any questions about using the enclosed software, please call the Celgene Customer Care Center at 1-888-423-5436.

Sincerely,

Jerome B. Zeldis, MD, PhD

Risks of REVLIMID® (lenalidomide)

- REVLIMID is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe
 life-threatening birth defects. If REVLIMID is used during pregnancy, it can cause birth defects or
 embryo-fetal death. REVLIMID must not be used by pregnant females and females who are able
 to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking REVLIMID
- REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients
- REVLIMID causes a higher chance for blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis), and lungs (pulmonary embolism). To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine

REVLIMID in combination with dexamethasone is indicated for the treatment of multiple myeloma (MM) patients who have received at least one prior therapy.

REVLIMID is indicated for patients with transfusion-dependent anemia due to Low- or Intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.







Revlimid REMS™

At-A-Glance

Important information about REVLIMID[®] (lenalidomide) and the REVLIMID Risk Evaluation and Mitigation Strategy (REMS)[™] program

- REVLIMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called "REVLIMID REMSTM" (formerly known as the RevAssist® program)
- Only prescribers and pharmacies certified by the REVLIMID REMS[™] program can prescribe and dispense REVLIMID to patients who are enrolled and meet all the conditions of the REVLIMID REMS[™] program
- Information about REVLIMID and the REVLIMID REMS[™] program can be obtained by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center toll-free at 1-888-423-5436

For more information about REVLIMID and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.



Revlimid REMS™



Initial prescription (for all patients unless otherwise noted)

- 1. For females of reproductive potential, obtain 2 negative pregnancy tests sensitive to at least 50 mIU/mL, even if continuous abstinence is the chosen method of birth control. One test must be obtained 10 to 14 days and one test within 24 hours prior to writing an initial prescription for REVLIMID® (lenalidomide).
- Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open REVLIMID capsules.
- Obtain, review, and complete the REVLIMID® (lenalidomide)
 Patient-Physician Agreement Form online at
 www.CelgeneRiskManagement.com, with the CD-ROM
 software, or by calling the Celgene Customer Care Center for
 assistance at 1-888-423-5436.
 - Males (adults and children)
 - Females of reproductive potential include <u>all</u> females who are menstruating, amenorrheic from previous medical treatments, under 50 years of age, and/or perimenopausal, and do not qualify for the females not of reproductive potential category
 - Females not of reproductive potential include females who have been in natural menopause for at least
 24 consecutive months, or who have had a hysterectomy and/or bilateral oophorectomy, or female children who have not started menstruating
- 4. Send the completed and signed REVLIMID® (lenalidomide) Patient-Physician Agreement Form online through www.CelgeneRiskManagement.com, or to the Celgene Customer Care Center by faxing to 1-888-432-9325.
- Instruct female patients to complete a brief initial mandatory confidential survey at www.CelgeneRiskManagement.com, or by calling 1-888-423-5436, prior to prescriber obtaining an authorization number.
 - Males do not need to complete the initial survey
- Complete a <u>prescriber</u> brief mandatory confidential survey by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center at 1-888-423-5436, for every patient before each prescription is written.
 - You will need to enter the following information:
 - Prescriber's identification number
 - Patient's identification number
 - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)

- 7. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
- 8. Send the prescription to a certified pharmacy.

Subsequent prescriptions (for all patients unless otherwise noted)

- For females of reproductive potential, obtain scheduled pregnancy tests weekly during the first 4 weeks of use; then pregnancy testing should be repeated every 4 weeks in females with regular menstrual cycles. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks.
- Provide mandatory counseling: no drug sharing, no blood or sperm donation, and appropriate contraceptive use. Patients should be instructed to not extensively handle or open REVLIMID capsules.
- Instruct patient to complete a brief mandatory confidential survey as scheduled, prior to prescriber obtaining an authorization number and filling the prescription.
 - Monthly:
 - Males (adults and children)
 - Females of reproductive potential (adults and children)
 - Female children not of reproductive potential
 - Every 6 months:
 - Adult females not of reproductive potential
- 4. Complete a <u>prescriber</u> brief mandatory confidential survey by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center at 1-888-423-5436, for every patient before each prescription is written.
 - You will need to enter the following information:
 - Prescriber's identification number
 - Patient's identification number
 - Date and result of patient's last pregnancy test(s) (if applicable); valid only for 7 days from date of last pregnancy test
 - Average daily dose
 - Total number of days supplied (cannot exceed 28 days)
- 5. An authorization number will be issued upon completion of the survey and must be written along with the patient risk category on the prescription. Authorization numbers are valid for 7 days from date of last pregnancy test for females of reproductive potential and 30 days from the date it is issued for all other patients. No automatic refills or telephone prescriptions are permitted.
- 6. Send the prescription to a certified pharmacy.

Revlimid REMS™

Prescriber Enrollment Form

All prescribers must be certified to prescribe REVLIMID® (lenalidomide). To become certified the prescriber must:

- 1. Complete the Prescriber Enrollment Form, which is required for REVLIMID REMS™ (formerly known as the RevAssist® program) certification.
- 2. Agree to steps on the following page that <u>must</u> be followed with every patient.

To submit this form electronically, please go to www.CelgeneRiskManagement.com.

To submit this form via fax, please complete the following page and fax it to 1-888-432-9325.

REVLIMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID provided adequate precautions are taken to avoid pregnancy.

Please review the steps on the following page that <u>must</u> be followed with every patient.



REVLIMID REMS™ Prescriber Enrollment Form

When prescribing REVLIMID® (lenalidomide), I agree to:

- Provide patient counseling on the benefits and risks of REVLIMID therapy, including Boxed Warnings
- Submit a completed REVLIMID® (lenalidomide) Patient-Physician Agreement Form for each new patient
- Provide contraception and emergency contraception counseling with each new prescription prior to and during REVLIMID treatment
- Provide scheduled pregnancy testing for females of reproductive potential and verify negative pregnancy test results prior to writing a new prescription or subsequent prescriptions
- Report any pregnancies in female patients or female partners of male patients prescribed REVLIMID immediately to Celgene Drug Safety (or Celgene Customer Care Center)
- Complete a mandatory and confidential <u>prescriber</u> survey online or by telephone for all patients and obtain a new authorization number for each prescription written and include this authorization number on the prescription
- Facilitate female patient compliance with an initial mandatory confidential patient survey online or by telephone
- Prescribe no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
- Contact a REVLIMID REMS™ certified pharmacy to fill the prescription
- Return to Celgene all REVLIMID capsules that are returned by patients. Shipping fees will be paid by Celgene Corporation. To arrange returns, call the Celgene Customer Care Center
- Remind patients to return all REVLIMID capsules to Celgene Corporation or their REVLIMID prescriber, or to the pharmacy that dispensed the REVLIMID to them
- Re-enroll patients in the REVLIMID REMS[™] program if REVLIMID is required and previous therapy with REVLIMID has been discontinued for 12 consecutive months

Please fill out the spaces below	w completely.		
Prescriber Name			
Degree: MD/DO/PA/NP/Fellow/N	Medical Resident		
Specialty			
Prescriber Identification Number	(eg, DEA Number, Social Security Numl	per, NPI Number, etc.)	
Please indicate which office(s)	will receive REVLIMID REMS™ mater	ials and updates:	
Primary Office Name			
		ZIP Code	
Phone	Ext	Fax	
Email Address			
City	State	ZIP Code	
Phone	Ext	Fax	
Email Address			
I understand that if I fail to con will not be honored at certified		.IMID REMS™ program, my prescriptions fo	or REVLIMID® (lenalidomide)
Prescriber Signature		Date	

Return this form to the Celgene Customer Care Center via fax or mail.

Mail to: Celgene Customer Care Center, 86 Morris Avenue, Summit, NJ 07901

Phone: **1-888-423-5436** Fax: **1-888-432-9325**

www.CelgeneRiskManagement.com







Revlimid REMS[™] REVLIMID Risk Evaluation and Mitigation Strategy (REMS)[™] program education and prescribing safety kit

Risks of REVLIMID® (lenalidom' 'e)

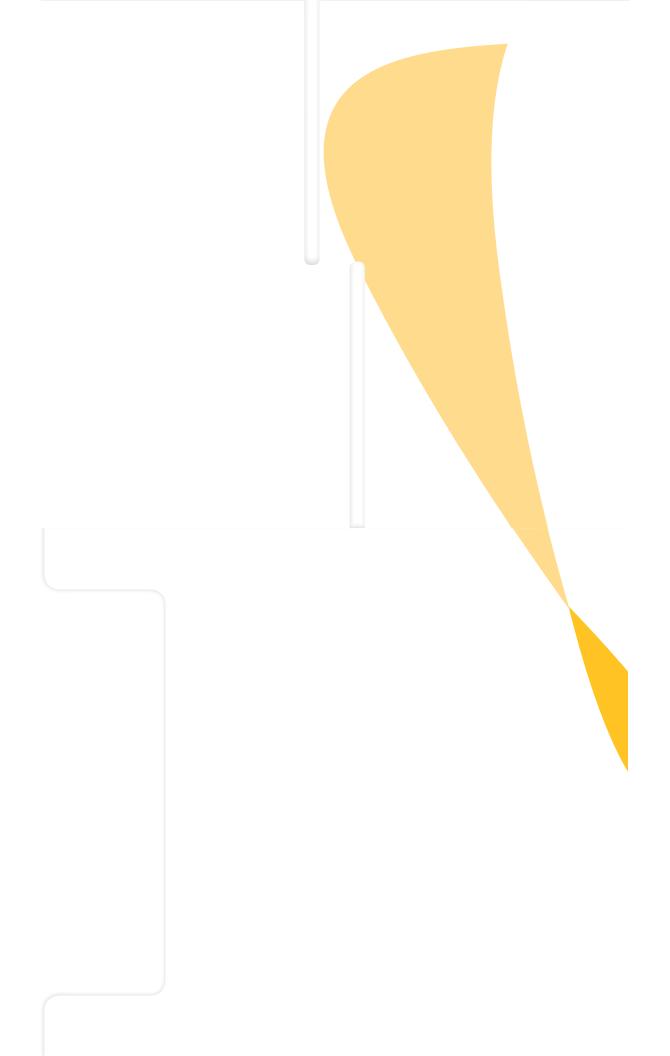
- REVLIMID is similar to the medicine thalidomide (THALOMID®). Thalidomide can cause severe life-threatening birth defects. If REVLIMID is used during pregnancy, it can cause birth defects or embryo-fetal death. REVLIMID must not be used by pregnant females and females who are able to get pregnant. Females who are able to get pregnant must avoid pregnancy while taking REVLIMID
- REVLIMID causes low white blood cells (neutropenia) and low platelets (thrombocytopenia) in most patients
- REVLIMID causes a higher chance for blood clots in your arteries (heart attacks and strokes), veins (deep vein thrombosis), and lungs (pulmonary embolism). To reduce this increased risk, most people who take REVLIMID will also take a blood thinner medicine

REVLIMID in combination with dexamethasone is indicated for the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy.

REVLIMID is indicated for the treatment of patients with transfusiondependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5g cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.





Revlimid REMS™

Prescriber quick reference guide

- 1. The prescriber provides comprehensive counseling.
- 2. The prescriber verifies negative pregnancy test for <u>all</u> female patients of reproductive potential.
- **3**. The prescriber completes REVLIMID® (lenalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene.
- 4. Female patients complete initial mandatory confidential survey by:
 - Visiting www.CelgeneRiskManagement.com, or
 - Calling Celgene Customer Care Center at 1-888-423-5436

Male patients do not need to complete the initial survey.

<u>All patients</u> must complete subsequent mandatory confidential surveys as outlined in the Prescriber Guide to REVLIMID REMS™ Program (formerly known as the RevAssist® program).

- **5**. The prescriber completes mandatory confidential survey and receives authorization number by:
 - Visiting www.CelgeneRiskManagement.com, or
 - Calling Celgene Customer Care Center at 1-888-423-5436
- **6**. The prescriber writes REVLIMID prescription and includes authorization number and patient risk category.
- 7. The prescriber sends prescription to certified pharmacy.

This flow sheet should be used only as a quick reference and only after reviewing all of the REVLIMID REMS™ procedures.

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.



Revlimid REMS™



Pharmacy Guide to

Revlimid REMS™

Risk Evaluation and Mitigation Strategy (REMS)™ Program

Important information about REVLIMID® (lenalidomide) and the REVLIMID REMS™ program

- REVLIMID is contraindicated in pregnant females and females capable of becoming pregnant. Females of reproductive potential may be treated with REVLIMID provided adequate precautions are taken to avoid pregnancy
- To avoid embryo-fetal exposure, REVLIMID is only available under a restricted distribution program called "REVLIMID REMS™" (formerly known as the RevAssist® program)
- Only prescribers and pharmacies certified with the REVLIMID REMS[™] program can prescribe and dispense the product to patients who are enrolled and meet all the conditions of the REVLIMID REMS[™] program
- Dispensing pharmacists must be educated on the REVLIMID REMS[™] program and on dispensing procedures for REVLIMID
- Information about REVLIMID and the REVLIMID REMS[™] program can be obtained by visiting www.CelgeneRiskManagement.com, or calling the Celgene Customer Care Center toll-free at 1-888-423-5436



Reference ID: 3627118

Table of contents

Guidelines for ordering, counseling, and dispensing REVLIMID® (lenalidomide)
Education and Counseling Checklist for Pharmacies6
Rules for dispensing and shipping6
Adverse drug experience reporting procedure for healthcare professionals7

Guidelines for ordering, counseling, and dispensing REVLIMID[®] (lenalidomide)

Dispensing pharmacies must be certified in the REVLIMID REMSTM pr must be educated in the following dispensing pr

Step 1. Review incoming REVLIMID pr

- A. Only accept prescriptions with an authorization number and patient risk category written on them.
- Authorization numbers are valid for 7 days fr patients of reproductive potential and 30 days fr No automatic refills or telephone pr
- o Faxed prescriptions are permissible depending on state laws
- B. Make sure the prescription is signed and dated.
- C. Confirm the prescription is written for a 4-week (28-day) supply or less.
- D. For subsequent prescriptions, verify ther existing prescription.

Step 2. Counsel patient

- A. Make sure a certified REVLIMID REMSTM
- B. Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist and ensur the appropriate boxes are checked of associated prescription.
- C. If the patient mentions adverse drug experiences that ar the use of REVLIMID and any suspected pr REVLIMID, make sure to document these experiences using acceptable documentation as noted on the checklist.
- Acceptable documentation examples:
- 1. Celgene Adverse Drug Event form and fax confi
- 2. Pharmacy log
- D. Report adverse drug experiences that ar REVLIMID to Celgene Drug Safety within 24 hours. See the Adverse Drug Experience Reporting Procedure on page 7 for mor

Guidelines for ordering, counseling, and dispensing REVLIMID® (lenalidomide) (continued)

Step 3. Obtain confirmation number from Celgene Customer Care

Prior to each prescription, contact Celgene Customer Care at **1-888-423-5436**, available 24 hours a day, 7 days a week. Eligible pharmacies may also use the Celgene REMS Pharmacy Portal at **www.CelgeneREMSPharmacyPortal.com**. Call your Celgene Account Manager to see if your pharmacy is eligible.

- Enter the pharmacy NABP number or DEA number
- Enter the authorization number written on the prescription
- o Enter the number of capsules and milligram strength being dispensed

Write the confirmation number and the date of receipt on the prescription. The confirmation number is only valid for 24 hours.

If you do not obtain a confirmation number, do not dispense REVLIMID.

Step 4. Dispensing

No Refills. A new prescription is required for each dispense. Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription.

Ensure the confirmation number has not expired, ie, dispense within 24 hours from confirmation number receipt. If more than 24 hours have elapsed, **Do Not Dispense**. You must call Celgene Customer Care at **1-888-423-5436** to cancel the first confirmation number and obtain a new confirmation number. For female patients of reproductive potential, ship the same day or hand to the patient within 24 hours.

Dispense each prescription with a Medication Guide and maintain a record on acceptable documentation.

Acceptable documentation examples:

- Signed Education and Counseling Checklist (if counseling pharmacist and dispensing pharmacist are the same)
- 2. Pharmacy log

Guidelines for ordering, counseling, and dispensing REVLIMID® (lenalidomide) (continued)

- D. Document the dispense date and maintain a r
- Acceptable documentation examples:
- 1. Shipping receipt
- 2. Pharmacy dispensing log
- E. Dispense no more than a 4-week (28-day) supply dispense. No automatic refills or telephone pr
- F. A signature is required for all shipping and dispense if picked up by patient.

Step 5. Perform drug accountability

- A. Pharmacy shall keep an inventory log for REVLIMID, by str inventory at all times.
- B. Do not transfer REVLIMID to another pharmacy without prior authorization fr
- C. Accept unused REVLIMID (previously dispensed) fr return the capsules to Celgene for pr

REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ Education and Counseling Checklist for Pharmacies

Ensure your patients know the risks

Before you are able to fill a prescription for REVLIMID® (lenalidomide), a checklist for each patient must be completed based on the patient risk category (written on the front of the Patient Prescription Form). When completing the checklist, be sure all the appropriate boxes are checked off (a) and the form is signed and dated. All boxes and spaces must be marked or filled in during counseling with the patient for every prescription. Retain a copy of the checklist and record of the associated prescription.



Be prepared to provide the following information for each checklist:

Authorization Number	Confirmation Number	Confirmatio
Pharmacy Name	Pharmacy Address (including City, State, ZIP Code)	y, State, ZIP Code)
Counselor Name	Work Phone Number	Extension
Patient Name	Patient Date of Birth	

mation Date

Rules for dispensing and shipping

Making sure before you release REVLIMID

<u>DO NOT DISPENSE OR SHIP REVLIMID TO A PATIENT UNLESS ALL THE FOLLOWING ARE DONE:</u>

- Prescription has an authorization number and patient risk category written on it
- You have obtained a confirmation number and a confirmation date
- You are shipping the product within 24 hours of obtaining the confirmation number and requesting confirmation of receipt. For females of reproductive potential, the product must be shipped the same day the confirmation number is obtained
- The Medication Guide is included with the prescription
- You confirm the prescription is no more than a 4-week (28-day) supply and there are
 7 days or less remaining on the existing REVLIMID prescription

For further information about REVLIMID, please refer to the full Prescribing Information, enclosed.

Adverse drug experience reporting procedure for healthcare professionals

Celgene is committed to ensuring patient safety through the monitoring of adverse drug experiences associated with the use of REVLIMID® (lenalidomide).

Please report adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID to Celgene using any of the following methods.

REPORTING TO CELGENE

- Email: drugsafety@celgene.com
- Telephone: 1-908-673-9667
- Toll-free: 1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Celgene Customer Care Center)
- Fax: 1-908-673-9115
- Mail to: Global Drug Safety & Risk Management, Celgene Corporation, 300 Connell Dr., Suite 6000, Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of REVLIMID and any suspected pregnancy occurring during the treatment with REVLIMID may also be reported to the FDA MedWatch Reporting System using any of the following methods:

- Online at: https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
- Telephone: 1-800-FDA-1088
- Fax: 1-800-FDA-0178
- Mail to: MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

For more information about REVLIMID® (lenalidomide) and the REVLIMID REMS™ program, please visit www.CelgeneRiskManagement.com, or call the Celgene Customer Care Center at 1-888-423-5436.

Celgene Corporation 86 Morris Ave Summit, NJ 07901

REVLIMID is only available under a restricted distribution program, **REVLIMID** REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.







REVLIMID® is a registered trademark of Celgene Corporation. REVLIMID REMSTM is a trademark of Celgene Corporation. © 2014 Celgene Corporation

REMS-REV14441



REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the RevAssist® program) education and prescribing safety

Authorization No.:	Confirmation No.:	Confirmation Date:	
Pharmacy Name:			
Pharmacy Address:			
·		Ext.:	
		n:	
Tilok Gategory.			J
Checklist for female patients of r	eproductive potential		
☐ I will make sure that patients are a	aware that they will receive the Medication G	uide along with their prescription	
I COUNSELED ADULTS AND CHILDRE	EN ON:		
☐ Potential embryo-fetal toxicity			
☐ Not taking REVLIMID® (lenalidomic	de) if pregnant or breastfeeding		
rings, or implants), or partner's vas		normonal (birth control pills, hormonal patches, injection tethod of birth control—male latex or synthetic condom tith a male	
☐ Continuing to use at the same tim 4 weeks before taking REVLIMID, v they have sex with a male, or abs	while taking REVLIMID, during dose interruptic	st 1 additional effective method of birth control beginnin ons, and for at least 4 weeks after stopping REVLIMID e	g at least very time
	e rest of their treatment in females with regula	uring the first 4 weeks of use. Thereafter, pregnancy tear or menstrual cycles or no cycle at all. If menstrual cycles	
■ The need to stop taking REVLIMID healthcare provider immediately) right away in the event of becoming pregnar	nt, or if they think for any reason they may be pregnant	, and to call their
Possible side effects include neutro	penia, thrombocytopenia, deep vein thrombosi	s, and pulmonary embolism as well as risk of myocardial	infarction and stro
☐ The need for del 5q MDS patients to	schedule a blood test every week for the first 8	weeks and monthly thereafter to monitor blood counts wh	nile taking REVLIMI
•	vith anyone-especially with females who can		
•	REVLIMID (including dose interruptions) and for	or 4 weeks after stopping REVLIMID	
□ Not breaking, chewing, or opening	'		
Instructions on REVLIMID dose ar	id administration		
Milligram (mg) Strength	Number of Capsules	Dispensed	
FEMALE CHILDREN (<18 YEARS OF AG	iE):		
☐ Parent or legal guardian must have	e read the REVLIMID REMS™ education mate	erial and agreed to ensure compliance	
Checklist for female patients not a hysterectomy, and/or bilateral (ause for at least 24 consecutive months,	
☐ I will make sure that patients are a	ware that they will receive the Medication Gu	ide along with their prescription	
I COUNSELED ADULTS AND CHILDRE	EN ON:		
Possible side effects include neutr myocardial infarction and stroke	openia, thrombocytopenia, deep vein thromb	osis, and pulmonary embolism as well as risk of	
☐ The need for del 5q MDS patients counts while taking REVLIMID	to schedule a blood test every week for the	first 8 weeks and monthly thereafter to monitor blood	İ
3 .	vith anyone-especially with females who can	0 1 0	
	REVLIMID (including dose interruptions) and fo	or 4 weeks after stopping REVLIMID	
□ Not breaking, chewing, or opening			
□ Instructions on REVLIMID dose ar			
Milligram (mg) Strength	Number of Capsules	Dispensed	
FEMALE CHILDREN (<18 YEARS OF AG	E):		

☐ I will make sure that patients are aware that they will receive the Medication Guide along with their prescription
I COUNSELED ADULTS AND CHILDREN ON:
□ Potential embryo-fetal toxicity and contraception (wearing a latex or synthetic condom every time when engaging in sexual intercourse with a female who can get pregnant)
□ Female partners of males taking REVLIMID® (lenalidomide) must call their healthcare provider right away if they get pregnant
Possible side effects include neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism as well as risk of myocardial infarction and stroke
☐ The need for del 5q MDS patients to schedule a blood test every week for the first 8 weeks and monthly thereafter to monitor blood counts while taking REVLIMID
□ Not sharing REVLIMID capsules with anyone—especially with females who can get pregnant
□ Not donating blood or sperm while taking REVLIMID (including dose interruptions) and for 4 weeks after stopping REVLIMID
□ Not breaking, chewing, or opening REVLIMID capsules
□ Instructions on REVLIMID dose and administration
Milligram (mg) Strength Number of Capsules Dispensed
MALE CHILDREN (<18 YEARS OF AGE):
□ Parent or legal guardian must have read the REVLIMID REMS™ education material and agreed to ensure compliance
All boxes and spaces must be marked or filled in during counseling with the patient for every prescription.
Counselor Signature: Date:

For more information about REVLIMID and the REVLIMID REMS™ program, please visit **www.CelgeneRiskManagement.com**, or call the Celgene Customer Care Center at **1-888-423-5436**.

Celgene Corporation 86 Morris Ave Summit, NJ 07901

Checklist for male patients

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS, enclosed.







Celgene REMS Programs Pharmacy Training: REVLIMID REMS"

Section 1: What Is a REMS?







- What is a REMS?
- Celgene REMS programs
- Pharmacy staff knowledge check

What is a REMS?



- REMS stands for Risk Evaluation and Mitigation Strategies
- REMS programs are mandated by the US Food and Drug Administration (FDA)
- According to the FDA, a REMS program is:
- A strategy to manage a known or potential serious risk associated with a drug or biological product
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks

Celgene REMS programs



- Celgene has REMS programs for THALOMID[®] (thalidomide), REVLIMID[®] (lenalidomide), and POMALYST[®] (pomalidomide):
- THALOMID REMS" program (formerly known as the *S.T.E.P* program) for THALOMID
- REVLIMID REMS™ program (formerly known as the RevAssist program) for REVLIMID
- POMALYST REMS[™] for POMALYST
- If these treatments are used during pregnancy, they can cause serious birth defects or embryo-fetal death
- The goals of these REMS programs are:
- To prevent the risk of embryo-fetal exposure to these treatments
- To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment

Celgene REMS programs (continued)



For more information on Celgene REMS programs:

- Call Celgene Customer Care at 1-888-423-5436
- Visit the specific product website

Did you know?

Celgene Customer Care has Compliance Specialists to educat pharmacy staff on Celgene REMS program guidelines and co

Pharmacy staff knowledge check



- REMS stands for Risk Evaluation and Mitigation Strategies.
- A. True
- B. False

Correct Answer: A. True

- REMS stands for Risk Evaluation and Mitigation Strategies
- A REMS is a strategy to manage a known or potential serious associated with a drug or biological product





- Who mandates REMS programs?
- A. Celgene
- B. The FDA
- C. The EPA

Correct Answer: B. The FDA

- REMS programs are mandated by the FDA
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks





- exposure and to inform prescribers, patients, and pharmacies Celgene REMS programs are mandated to avoid embryo-fetal serious risks and safe-use conditions for each treatment.
- A. True
- B. False

Correct Answer: A. True

- The goals of the Celgene REMS programs are:
- To prevent the risk of embryo-fetal exposure to these treatments
- To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for each treatment

Celgene REMS Programs Pharmacy Training: REVLIMID REMS

Section 2: Program Requirements for Patients and Prescribers



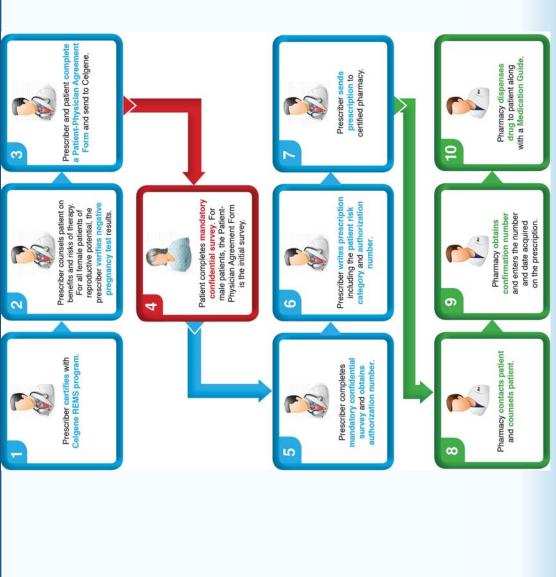




- Program overview
- Certification and enrollment requirements for prescribers and patients
- Patient risk categories
- Contraception requirements
- Pregnancy test requirements
- Mandatory confidential surveys
- Pharmacy staff knowledge check

Celgene REMS program overview





Certification and enrollment requirements for prescribers and patients



- Prescribers must be certified with the Celgene REMS program in order to prescribe a product with a REMS program for a patient
- Prescribers must complete the REMS program enrollment and agree to comply with the program requirements
- Prescribers are required to enroll patients in a specific Celgene REMS program before starting a patient on a therapy with a
- Patients must enroll in the REMS program and agree to comply with the program requirements

Patient risk categories



- There are 6 different patient risk categories for patients enrolled Celgene REMS programs:
- Adult female of reproductive potential
- Female child of reproductive potential
- Adult female not of reproductive potential
- Female child not of reproductive potential
- Adult male
- Male child





Females of reproductive potential include all females who:

Are menstruating

Are amenorrheic from previous medical treatments

Are under 50 years of age

Are perimenopausal

Do not qualify for the females not of reproductive potential category

The risk categories for females of reproductive potential are:

Adult female of reproductive potential

Female child of reproductive potential





Females not of reproductive potential include females who:

Have been in natural menopause for at least 24 consecutive months

Have had a hysterectomy and/or bilateral oophorectomy

Have not started menstruating

The risk categories for **females not of reproductive potential**

Adult female not of reproductive potential

Female child not of reproductive potential





Males include adults and children (under 18 years of age)

The risk categories for males are:

- Adult Male
- Male Child

Contraception requirements: Females of reproductive potential



- Female patients of reproductive potential must either completely abstain from heterosexual sexual contact or must use 2 methods of reliable contraception
- Reliable contraceptive methods include
 using at the same time at least 1 highly
 effective method and at least 1 additional
 method of birth control every time they
 have sex with a male
- Reliable contraceptive methods must be started at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

Highly effective

Tubal ligation

Intrauterine device (IUD)

Hormonal (birth control patches, injections, vaginal implants)

Partner's vasectomy

Additional effective

Male latex or synthetic

Diaphragm

Cervical cap

Remind patients that not having any sexual intercourse is the only birth c method that is 100% effective.

Females of reproductive potential (continued) Contraception requirements:



Unacceptable contraception methods:

- Progesterone-only "mini-pills"
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield
- A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception

Contraception requirements: Males



- Male patients must use a latex or synthetic condom:
- Every time they have sexual intercourse with a female of reproductive potential
- Even if they have undergone a successful vasectomy
- During therapy (including dose interruptions)
- For 4 weeks after discontinuation of therapy

Remind patients that not having any sexual intercourse is the only birth c method that is 100% effective.





- For females of reproductive potential, prescriber must obtain pregnancy test:
- 10 to 14 days before an initial prescription
- Within 24 hours before an initial prescription
- The pregnancy test must be sensitive to at least 50 mIU/mL
- Subsequent pregnancy testing should occur:
- Weekly during the first 4 weeks of use, then
- Every 4 weeks if patient has regular menses or no menses,
- Every 2 weeks if irregular menses





If pregnancy does occur:

- Treatment must be immediately discontinued
- Any suspected embryo-fetal exposure must be reported immediately Celgene Global Drug Safety and reported to the FDA
- Celgene Global Drug Safety: 1-800-640-7854
- FDA MedWatch number: 1-800-FDA-1088
- The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling





- All patients must complete brief mandatory confidential surveys in to obtain treatment
- Surveys can be completed via CelgeneRiskManagement.com o calling Celgene Customer Care at 1-888-423-5436

Patient Manda	Patient Mandatory Confidential Survey Schedule for Adults and	or Adults and
Risk category	Initial Prescription	Subsequent
Females of reproductive potential	Complete appropriate survey	Monthly surv
Females not of reproductive potential	Complete appropriate survey	Child: Monthly Adult: Survey
Males	Do not need to take initial survey	Monthly surv





 How many patient risk categories are there in the Celgene REMS programs?

• A. 3

• B. 5

• C. 6

Correct Answer: C. 6

Celgene REMS program patient risk categories	risk categories
Adult	Child (under 18)
Adult female of reproductive potential	Female child of reproductive potential
Adult female not of reproductive potential	Female child not of reproductive potential
Adult male	Male child

Celgene Confidential: For Celgene Business Use Only

Pharmacy staff knowledge check (continued)



- For all Celgene REMS products, female patients of reproductive potential must take a pregnancy test:
- A. 10-14 days before first prescription
- B. Within 24 hours before first prescription
- C. 10-14 days and within 24 hours before first prescription

Correct Answer:

C. 10-14 days and within 24 hours before first prescrip

- Prescribers must obtain 2 negative pregnancy tests before the prescription for females of reproductive potential:
- 10 to 14 days before an initial prescription
- Within 24 hours before an initial prescription





- Which is a highly effective method of contraception?
- A. Male latex or synthetic condom
- B. IUD
- C. Female condom

Correct Answer: B. IUD

Highly effective methods	Additional effective methods
Tubal ligation	Male latex or synthetic co
Intrauterine device (IUD)	Diaphragm
Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Cervical cap
Partner's vasectomy	

Celgene REMS Programs Pharmacy Training: REVLIMID REMS

Section 3: Program Requirements for Pharmacies







- Training and certification requirements
- Pharmacy compliance
- Pharmacy staff knowledge check





- Celgene REMS program certified counselors must:
- Be licensed healthcare professionals
- Complete the Celgene-sponsored training on all required modules annually and pass certification exam with 100% accuracy
- Educate patient by telephone or in person before treatment be dispensed
- Understand and counsel patients on the potential for birth or death to an unborn baby
- Counsel patients on possible side effects
- Other pharmacy staff involved in dispensing treatment must:
- Be educated on the guidelines for dispensing

Pharmacy compliance



- Pharmacy manager responsibilities
- Educate all staff regarding dispensing guidelines
- Includes floater pharmacists, pharmacy technicians, or anyone handling the product
- ComplianceWire" and advise Celgene of inactive counselors Make sure counselors are registered and certified in
- Complete and return all documentation that pertains to non-compliance

Did you know? Pharmacy managers can call Celgene Customer Car **5436** with questions. Ask for Risk Compliance.





- Pharmacy deviations
- conditions that lead to deviations from Celgene REMS programs The pharmacy will be required to investigate and correct
- Celgene will work with the pharmacy to implement appropriate corrective actions and a timeframe for those actions
- If corrective actions are not successful, Celgene may take additional action, up to and including deactivation of the pharmacy





- A High Risk Deviation is:
- Any action taken by the pharmacy that is inconsistent or non-compliant with the Celgene REMS program that increases the risk of embryo-fetal exposure
- pharmacy's negligent or willful disregard to the Celgene Any action that occurs on a consistent basis that shows **REMS** program requirements
- will be deactivated and will no longer be permitted to dispense If there are 3 High Risk Deviations within 1 year, the pharmacy product





- Celgene REMS program certified counselors must complete the Celgene-sponsored training:
- A. Annually
- B. Every 6 months
- C. Every 2 years

Correct Answer: A. Annually

Counselors must complete the Celgene-sponsored training annually





- All counselors must pass the certification test with an accuracy of:
- A. 100%
- B. 90%
- C. 95%

Correct Answer: A. 100%

Counselors must pass the certification exam with 100% accuracy

Pharmacy staff knowledge check (continued)



- Celgene may deactivate pharmacies for deviations.
- A. True
- B. False

Correct Answer: A. True

- The pharmacy will be required to investigate and correct conditions that lead to deviations from Celgene REMS programs
- If corrective actions are not successful, Celgene may take additional action, up to and including deactivation of the pharmacy

Celgene REMS Programs Pharmacy Training: REVLIMID REMS

Section 4: Guidelines for Counseling



In this section



- Counseling for female patients of reproductive potential
- Counseling for female patients not of reproductive potential
- Counseling for male patients
- Additional counseling for all patients taking REVLIMID[®] (lenalidomide)
- Pharmacy staff knowledge check



The sequence of this section is based on the Education and Counseling Checklis for Pharmacies.

Remember to fill out this checklist for every patient for every pr

Counseling for female patients of reproductive potential



 Make sure that patients are aware that they will receive the Medication **Guide** along with their prescription

- Potential embryo-fetal toxicity
- Not taking treatment if pregnant or breastfeeding
- Using at the same time at least 1 highly effective method and at least 1 additional effective method of birth control every time they have sex with a male, or abstaining from sex with a male
- device (IUD), hormonal (birth control pills, hormonal patches, injections, Highly effective methods of contraception: Tubal ligation, intrauterine vaginal rings, or implants), or partner's vasectomy
- Additional effective methods of contraception: Male latex or synthetic condom, diaphragm, or cervical cap

Counseling for female patients of reproductive potential (continued)



- Continuing to use at the same time at least 1 highly effective method and at least 1 additional effective method of birth
- Beginning at least 4 weeks before treatment
- During treatment
- During dose interruptions
- For at least 4 weeks after stopping treatment
- Every time they have sex with a male, or abstaining from sex with a male

Counseling for female patients of reproductive potential (continued)



- Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use
- Pregnancy testing should be repeated:
- Every 4 weeks during the rest of their treatment in females regular menstrual cycles or no cycle at all
- If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks
- The need to stop treatment right away in the event of becoming pregnant, or if they think for any reason they may be pregnant and to call their healthcare provider immediately

Counseling for female patients of reproductive potential (continued)



COUNSEL ADULTS AND CHILDREN ON:

- Not sharing capsules with anyone—especially with females who
- Not donating blood during treatment (including dose interruptions) weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
- It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

FOR FEMALE CHILDREN (<18 YEARS OF AGE):

 Parent or legal guardian must have read the Celgene REMS program education material and agreed to ensure compliance

Counseling for female patients not of reproductive potential



 Make sure that patients are aware that they will receive the **Guide** along with their prescription

- Not sharing capsules with anyone—especially with females who pregnant
- Not donating blood during treatment (including dose interruptions) 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
- It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

Counseling for female patients not of reproductive potential (continued)



FOR FEMALE CHILDREN (<18 YEARS OF AGE):

- program education material and agreed to ensure compliance Parent or legal guardian must have read the Celgene REMS
- Parent or legal guardian must inform the child's doctor when the child begins menses





 Make sure that patients are aware that they will receive the Medication Guide along with their prescription

- Potential embryo-fetal toxicity and contraception
- engaging in sexual intercourse with a female who can get Wearing a latex or synthetic condom every time when pregnant
- Female partners of males receiving treatment must call their healthcare provider right away if they get pregnant





COUNSEL ADULTS AND CHILDREN ON:

- Not sharing capsules with anyone—especially with females who can
- Not donating blood or sperm during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Instructions on dose and administration
- It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist

FOR MALE CHILDREN (<18 YEARS OF AGE):

Parent or legal guardian must have read the Celgene REMS prog education material and agreed to ensure compliance

Additional counseling for all patients taking REVLIMID (lenalidomide)



COUNSEL ADULTS AND CHILDREN ON:

- deep vein thrombosis, and pulmonary embolism as well as risk Possible side effects include neutropenia, thrombocytopenia, of myocardial infarction and stroke
- For del 5q MDS patients, the need for weekly blood tests to be completed for the first 8 weeks and monthly thereafter to monitor blood counts while taking REVLIMID

Counsel patient to contact healthcare provider if experiencing an effects.

Pharmacy staff knowledge check



- Which of these is not something patients need to be counseled
- A. Not sharing capsules
- B. Not breaking, chewing, or opening capsules
- C. Wearing gloves while taking capsules

Correct Answer: C. Wearing gloves while taking capsule

- Patients must be counseled on:
- Not sharing capsules with anyone—especially with females who can get pregnant
- Not breaking, chewing, or opening capsules

Pharmacy staff knowledge check (continued)



- Female patients of reproductive potential must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control for 4 weeks after stopping treatment.
- A. True
- B. False

Correct Answer: A. True

- 1 highly effective method and at least 1 additional effective method of Female patients of reproductive potential must continue to use at the
- Beginning at least 4 weeks before treatment
- During treatment
- During dose interruptions
- For at least 4 weeks after stopping treatment
- Every time they have sex with a male, or abstaining from sex





- All patients must receive a Medication Guide along with their prescription.
- A. True
- B. False

Correct Answer: A. True

 Make sure that patients are aware that they will receive the Medication Guide along with their prescription

Celgene REMS Programs Pharmacy Training: REVLIMID REMS

Section 5: Guidelines for Dispensing







- Pharmacy and prescription requirements
- Dispensing guidelines
- Steps for dispensing
- Pharmacy staff knowledge check

Pharmacy and prescription requirements



- program and educated on the program and on dispensing procedures Dispensing pharmacies must be certified in the applicable Celgene the treatment
- Pharmacy must ensure that every prescription includes:
- Patient and prescriber demographics and contact information
- Patient risk category
- Dosing information and instructions
- Authorization number
- Prescriber signature
- Authorization numbers are valid for 7 days from the date of last pregnancy test for female patients of reproductive potential and 30 days from the date it is issued for all other patients
- No automatic refills or telephone prescriptions are permitted
- Faxed prescriptions are permissible depending on state laws

Dispensing guidelines



- Dispense no more than a 4-week (28-day) supply with the Medication Guide. A new prescription is required for further dispensing
- Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription
- Dispense or ship the product within 24 hours of obtaining and recording confirmation number
- For females of reproductive potential, product must be shipped the day confirmation number is obtained or picked-up within 24 hours obtaining confirmation
- Pharmacy is required to cancel the confirmation number if product provided to the patient within the required time frame
- Pharmacy must obtain a new confirmation number by calling Celgene Customer Care at 1-888-423-5436 when ready to ship or have the product picked-up

Dispensing guidelines (continued)



- When shipping, pharmacy must require a signature confirming
- Pharmacy shall keep an inventory log for the drug, by strength, reflecting its on-hand inventory at all times
- Do not transfer the drug to another pharmacy without prior authorization from Celgene
- Accept unused capsules (previously dispensed) from a patient or patient caregiver and return the capsules to Celgene for proper

Steps for dispensing



Review incoming prescriptions

- Only accept prescriptions with all of the following information:
- Patient and prescriber demographics and contact information
- Patient risk category
- Dosing information and instructions
- Authorization number
- Prescriber signature
- Make sure the prescription is signed and dated
- Confirm the prescription is written for a 4-week (28-day) supply or
- For subsequent prescriptions, verify there are 7 days or less of therapy remaining on the existing prescription





Counsel patient

- Patients must receive counseling from a Celgene REMS program certified pharmacy counselor
- Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist
- Make sure form is signed and dated by the counselor and appropriate boxes are checked off
- Keep a copy of the checklist and the associated prescription
- Please report adverse drug experiences that are suspected to be associated with the use of the drug and any suspected pregnancy occurring during the treatment





Obtain confirmation number from Celgene

- 24 hours a day, 7 days a week. Eligible pharmacies may also use the Celgene R Prior to each prescription, contact Celgene Customer Care at 1-888-423-5436, Pharmacy Portal at www.CelgeneREMSPharmacyPortal.com. Call your Manager to see if your pharmacy is eligible.
- Enter the pharmacy NABP number or DEA number
- Enter the authorization number written on the prescription
- Enter the number of capsules and milligram strength being dispensed 3
- Write the confirmation number and date on the prescription. Note: the only valid for 24 hours

4

 If you do not obtain a confirmation number, you are not permitted to product to the patient

If you have questions about the validity of the authorization or co numbers, call Celgene Customer Care.





Dispense prescription

- Include a Medication Guide with each prescription
- Document the dispense date on either the shipping receipt or pharmacy dispensing log
- Dispense or ship the product within 24 hours of obtaining and recording the confirmation number
- For females of reproductive potential, product must be shipped the same day confirmation number is obtained or handed to patient within 24 hours

Pharmacy staff knowledge check



- A confirmation number is valid for:
- A. 24 hours
- B. 7 days
- C. 30 days

Correct Answer: A. 24 hours

- The confirmation number is only valid for 24 hours
- product is not provided to the patient within the required time Pharmacy is required to cancel the confirmation number if

Pharmacy staff knowledge check (continued)



- Each prescription must have both an authorization number and a patient risk category written on it.
- A. True
- B. False

Correct Answer: A. True

- Only accept prescriptions with all of the following information:
- Patient and prescriber demographics and contact information
- Patient risk category
- Dosing information and instructions
- Authorization number
- Prescriber signature

Pharmacy staff knowledge check (continued)



- The pharmacy must dispense no more than a 4-week (28-day) supply.
- A. True
- B. False

Correct Answer: A. True

- Dispense no more than a 4-week (28-day) supply with the Medication Guide
- A new prescription is required for further dispensing

Revlimid REMS™

Patient Resource Pack

REVLIMID Risk Evaluation and Mitigation Strategy (REMS)™ program (formerly known as the RevAssist® program)

The Patient Resource Pack contains:

- Patient Guide to REVLIMID REMS[™] Program
- Emergency Contraception Brochure
- Medication Guide

REVLIMID is only available under a restricted distribution program, REVLIMID REMS™.

Please see full Prescribing Information, including Boxed WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, and Medication Guide, enclosed.





REVLIMID® is a registered trademark of Celgene Corporation. REVLIMID REMS $^{\text{TM}}$ is a trademark of Celgene Corporation.